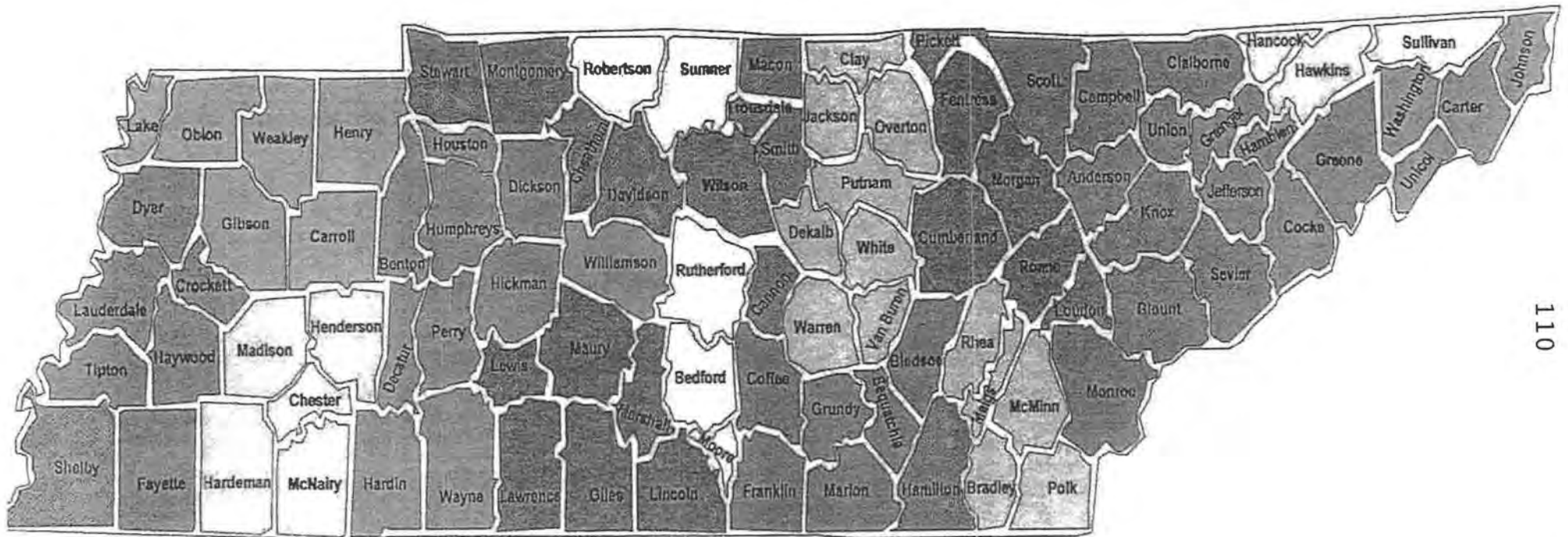


Attachment C 3.  
Tennessee Methadone Service Areas  
January 2002



110

**SUPPLEMENTAL- # 1**

March 25, 2013  
12:15pm

## Possible Methadone Service Areas for NR Methadone Clinic Locations

<u>MSA #</u>	<u>County</u>	<u>Popn</u>	<u>RSA #</u>	<u>County</u>	<u>Popn</u>
1	Washington	107,200	13	Hickman	22300
	Johnson	17500		Perry	7600
	Carter	56700		Wayne	16800
	Unicoi	17700		Dickson	43200
	S/T	199,100		Humphreys	17900
2	Sullivan	153,000	14	Houston	8100
	Hawkins	53500		Hardin	25600
	Hancock	6800		Decatur	11700
	S/T	213,300		Benton	16500
				S/T	169700
3	Greene	62900	15	Montgomery	134800
	Cocke	33600		Stewart	12400
	Hamblen	58100		Cheatham	35900
	Jefferson	44300		S/T	183100
	Grainger	20700			
4	S/T	219600	16	Williamson	126600
	Claiborne	29900		Sumner	130400
	Union	17800		Robertson	54400
	Campbell	39900		S/T	184800
	Scott	21100			
5	Anderson	71300	17	Madison	91800
	S/T	180000		McNairy	24700
	Sevier	71200		Chester	15600
	Blount	105800		Henderson	25500
	Monroe	39000		Hardeman	28100
6	S/T	216000	18	S/T	185700
	Cumberland	46800		Weakley	34900
	Morgan	19800		Henry	31100
	Roane	51900		Carroll	29500
	Loudon	39100		Gibson	48200
7	Fentress	16600	19	Obion	32500
	Pickett	4900		Lake	8000
	S/T	179100		S/T	184200
	Putnam	62300		Dyer	37300
	Overton	20100		Lauderdale	27100
	Jackson	11000		Tipton	51300
	Warren	38300		Haywood	19800
	Gray	8000		Crockett	14500
				Fayette	28800

	White	23100		S/T	178800
	Dekalb	17400			
	Van Buren	5500			
	S/T	185700			
8	Bradley	88000			
	Polk	16100	20	Knox	382000
	McMinn	49000	21	Hamilton	307900
	Meigs	11100	22	Davidson	569900
	Rhea	28400	23	Shelby	897500
	S/T	192600			
9	Bledsoe	12400		RSA	# Current PTs Rate/100K
	Sequatchie	11400		1	55 27.6
	Marion	27800		2	27 12.7
	Grundy	14300		3	119 54.2
	Franklin	39300		4	149 82.8
	Coffee	48000		5	146 67.6
	S/T	153200		6	196 109.4
				7	153 82.4
10	Rutherford	182000		8	77 40.0
	Bedford	37600		9	45 29.4
	Moore	5700		10	37 16.4
	S/T	225300		11	32 21.8
				12	62 29.8
11	Wilson	88800		13	42 24.7
	Macon	20400		14	30 16.4
	Trousdale	7300		15	33 26.1
	Cannon	12800		16	33 17.9
	Smith	17700		17	53 28.5
	S/T	147000		18	56 30.4
				19	21 11.7
12	Maury	69500		20	440 77.2
	Marshall	26800		21	193 62.7
	Lincoln	31300		22	375 65.8
	Giles	29400		23	365 40.7
	Lewis	11400		Total	2739 48.1
	Lawrence	39900			
	S/T	208300			
				2845 no Zip	50.0

67/100K	Pop'n	152/100K
100	150,000	228
134	200,000	304
161	250,000	369

**LETTERS OF SUPPORT  
(TO DATE)**

March 25, 2013

12:15pm

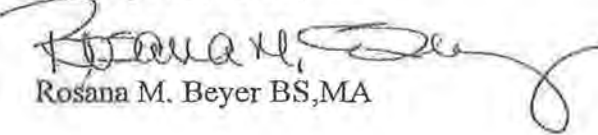
March 17, 2013  
8564 Horton Hwy.  
Greeneville, TN 37745

2013 MAR 21 AM 9:13

TO WHOM IT MAY CONCERN: I have worked with young people for over thirty years dealing with their educational, emotional, and physical everyday problems. For the majority of the young people I worked with, had used drugs or was using them on a daily basis to rid themselves of their physical and emotional pain.

Therefore, I firmly believe in a methadone clinic in the Johnson City area. We, the community, and the young people, would truly benefit from it conception.

Thank-you so much,



Rosana M. Beyer BS,MA

March 25, 2013

12:15pm

To Whom This May Concern,

2013 MAR 20 AM 9:07

My name is Kathy Ostertag, RN and I am writing in support of the Certificate of Need for an opiate treatment program (OTP) in Johnson City. I have no financial interest in the company trying to open the OTP.

I have worked at three OTPs in the Asheville, North Carolina area. In all three clinics, many of the patients come from the Tri Cities area and drive great distances, crossing the state line to get treatment. I believe that for every patient that made the trek, 2 or 3 did not. Distance and time are the leading barriers to getting treatment. You should worry about these people who don't get treatment. Statistically, 80% of addicts support their addiction through crime - theft, prostitution, forgery, etc.

Let me give you an example of a typical day in the life of a person/family in recovery who has made the brave choice to get help for their addiction: A young family living in the Johnson City area - one maybe both parents have struggled for years with addiction - but now they have hope - they have a place where they can get relief from the physical pain of addiction and the support of a staff of Nurses, Doctors, and highly qualified counselors to help them in this brave effort. Finally without the chain of addiction and the lifestyle that goes along with it - the father and mother now both have legitimate jobs are able to provide their families with a good and safe home - gained back the respect they had long ago lost for themselves. The one draw back is it is over an hour away on often dangerous roads in inclement weather. - So their day starts out with an alarm that rings at about 1:00 AM - they get up, get their kids up from a good nights sleep, place their sleeping children in the car for the long drive to Asheville - an hour or more away - arriving at about 3:00 AM at the treatment program to wait for the clinic to open at 5:00 AM - they arrive so early to ensure a place at the front of the line, as there are so many others their that have made the same long trip from your area that day - to facilitate getting back home earlier. They enter the clinic, they usually see their counselor, get their medication and usually several times a month have a urine drug screen - all of this taking at least an hour. Now they drive back home arriving there around 7:00 AM - and now there day begins - just like yours and mine. They get ready for work - get the kids' fed and ready for school and/or day care - leave the house to have a productive day just like the rest of us. Except this family has already had a full day. Now multiply this by 1000 people/families in treatment - This facility is NEEDED.

March 25, 2013

12:15pm

Ask yourselves is it fair that the residents of the Johnson City area should have to endure such hardship in order to gain their lives back. These are members of our community that you and I work with everyday – side by side – families just like yours and mine – wanting a better life for themselves and there children – should it be so hard for them – ask yourself that. I can't tell you how many times I have heard the words "Kathy – This place has saved my life". As a health care professional I can tell you there is nothing better, or more rewarding to know that you have helped to improve the lives of others – this program will change lives in your community.

For those who do make the drive, many, like the family I describe above, are under great stress struggling with the finances and time to make the commute. Many drop out of treatment because they can't afford the gas, or have work or family commitments that conflict. Dropping out of treatment often means relapsing back to drugs.

Companies want to open in the Tri Cities area because there is a desperate need. I understand locals are concerned about crime and property values. I can tell you first hand after 12 years working in addiction treatment – these facilities are good neighbors – going un noticed in their locations – supporting out reach programs in the community with education and support of community programs – these substance abuse treatment programs SAVE lives and FAMILIES and in turn help SAVE our communities. Many studies have shown that the far greater risk is the LACK of treatment.

Approve the CON. Lower crime. Lower drug use. Less disease. Compassionate care.

Sincerely,



Kathy Osterlag, RN



March 25, 2013

12:15pm

To whom it may concern,

Concerning the proposed methadone clinic in Johnson City.

I am in full support of it. Abstinence works in some people but not in others.

If you know you're going to get your daily dose you are more likely to be able to hold a job and live your life.

Prescription drug abuse is rampant in the area. Chasing that dose everyday is no fun.

Addiction knows no social or economic boundaries. It ranges from soccer moms to street junkies. No one wants to be a junkie and a clinic would provide them with a pathway to get clean without constantly trying to find drugs and come up with the money to buy them. That is where most of the crime comes in.

As far as crime around the clinic, that's what the police are for.

Please issue a certificate of need. The problems are just getting worse.

Thank you

*Ross Jackson*

Ross Jackson

PO Box 185

Chuckey, TN 37641



March 25, 2013

12:15pm

Joy Jackson

PO Box 185

Chuckey, TN 37641

March 18, 2013

2013 MAR 21 AM 9:14

Health Services and Development

Agency

The Frost Bldg. Third Floor

161 Rosa L. Parks Blvd.

Nashville, TN 37243

To Whom It May Concern:

As a citizen of Upper East Tennessee, I am writing in support of approval of a certificate of need for a methadone clinic in Johnson City.

Prescription drug and opiate addiction has become rampant in our area and is reflected in increased criminal activity, unemployment and the breakup of families.

No addict started out with the thought that he/she could become physically dependent on these drugs. No one wants to be a junkie. Many want to quit but do not know where to turn. A treatment clinic in our area could help many hundreds of addicts turn their lives around and once again be productive members of our society. They would be able to work and lead a normal life close to home. As it is now, addicts from the Tri-cities area must drive to Knoxville or Asheville, NC every day for treatment, which is nearly impossible while trying to hold down a job. Many will give up because of this limitation.

A methadone clinic in Johnson City would be a positive thing for this community and all of its citizens.

Thank you,



Joy Jackson

March 25, 2013

12:15pm

Tennessee Health Services And Development Agency  
Melanie M. Hill, Executive Director  
Frost Building, 3rd Floor  
161 Rosa L. Parks Boulevard  
Nashville, TN 37243

2013 MAR 21 AM 9:14

March 11, 2013

Ms. Hill:

I am writing you in support of Tri-Cities Holding's Certificate of Need for an opiate treatment program in Johnson City, Tennessee.

I have the unique advantage of treating over 1,000 opiate-addicted patients both in an opiate treatment program and a private physician's office. I have medically supervised methadone, buprenorphine and abstinence-based services to treat those suffering from opiate addiction. I have no financial interest in Tri-Cities Holdings, nor am I a part of the staff or management.

There are several points I wish your Agency to know about treating those suffering from opiate addiction.

1. Physician-based practices that offer buprenorphine treatment are significantly disadvantaged relative to opiate treatment programs:
  - a. These offices rarely provide counseling services, which are a critical component to treatment and a patient's ultimate path to independence
  - b. Private doctor's office don't have the same requirements for drug testing, attendance and group therapy that are critical to ensure compliance and a patient's commitment
  - c. The hours of operation of a doctor's office do not meet a patient's need to balance work and family commitments
  - d. Addicts are co-mingled with the other patients in the office which creates shame and discomfort
  - e. Staff at opiate treatment programs (nurses, counselors, doctors, etc.) are specifically trained and credentialed to treat the specific needs of those suffering from opiate addiction
  - f. When compared to the cost and services of an opiate treatment program, doctors' offices are significantly over-priced
2. Johnson City is trading the perceived problems of a methadone clinic with the very real costs of opiate addiction. Distance plays a significant role in treatment. In my Atlanta-based practices, I frequently see patients who travel great distances because the community they live in does not want a clinic or is too small to support a clinic. As you know, patients who are just entering treatment must come every day. This is the precise time that they are most vulnerable to relapse, and this distance places a tremendous burden on them.

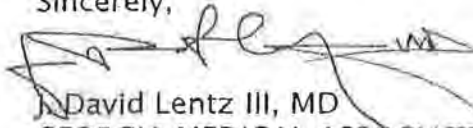
Further, for every patient that travels far for treatment, he or she will tell you they know 2 or 3 addicts that want treatment, but cannot make the commitment of time or money associated with a long daily commute.

Untreated addicts commit crime to support their habit, leave their families, get incarcerated, and clog emergency rooms. In keeping a clinic out, Johnson City is inviting in many more problems. March 25, 2013 12:15pm

3. Whatever the perceived problems of opiate treatment programs, Johnson City has exported them to the nearest communities that will support treatment. Does this seem like the right thing to do?
4. The perceived problems of opiate treatment programs are just that, perceived. There are nearly 1,300 of these clinics in the US. If they were as bad as the Johnson City officials have made them out to be, do you think they would be tolerated? The fact is, these clinics open and operate with a whimper, not a bang. The worst problems are parking and smoking, which pale in comparison to theft, prostitution, HIV, and broken families.
5. Most of the opposition that I have read is from uninformed people who perpetuate myths. Have you heard from former patients, staff or neighboring businesses? Asheville has five of these clinics, yet it's a wonderful city.
6. Speaking of myths, here are some doozies: "Methadone is just trading one drug for another. Addicts should just go cold turkey." Less than 10% of opiate addicts can withdraw "cold turkey" without relapse. Many pain pills are just as addictive as heroin and substantial research has shown that abstinence-based withdraw is far less successful than medication-based treatment.
7. Johnson City's problems may get worse. "Pain mills" and other diversion operations are being successfully identified and shut down. That's the good news. However, if pain pills addicts have no treatment, they will likely turn to heroin, which has become cheaper and easier to obtain in most communities.

I encourage you to take an objective review of the facts. Doing so will lead you to the decision that this project is best for the community.

Sincerely,



David Lentz III, MD  
GEORGIA MEDICAL ASSOCIATES PC  
2121 Fountain Drive  
Suite A  
Snellville, GA 30078

## NOTIFICATION REQUIREMENT

March 25, 2013

12:15pm

**Tri-Cities Holdings LLC**  
d/b/a Trex Treatment Center  
6555 Sugarloaf Parkway Suite 307-137  
Duluth, GA 30097

Phone: 404-664-2616

E-mail:  
swkester@gmail.com

March 5, 2013

VIA CERTIFIED MAIL/RETURN RECEIPT REQUESTED

Rep. James (Micah) Van Huss  
R-Jonesborough District 6  
301 6th Avenue North  
Suite 23 Legislative Plaza  
Nashville, Tennessee 37243

Mayor Dan Eldridge  
Washington County Mayor's Office  
103 W. Main St.  
Jonesborough, Tennessee 37659

Senator Rusty Crowe  
R-Johnson City District 3  
301 6th Avenue North  
Suite 8 Legislative Plaza  
Nashville, Tennessee 37243

Mayor Jeff Banyas  
Municipal & Safety Building  
601 E. Main Street  
Johnson City, Tennessee 37601

Gentlemen:

In accordance with Tenn. Code Ann. Section 68-11-1607, please be advised that an application for a nonresidential methadone treatment facility to be located at 4 Wesley Court, Johnson City, TN 37601 has been filed with the Tennessee Health Services and Development Agency by Tri-Cities Holdings LLC d/b/a Trex Treatment Center.

Sincerely,  
Tri-Cities Holdings LLC

Steve Kester, Manager.

SWK/jd

CERTIFIED MAIL™ RECEIPT		
(Domestic Mail Only; No Insurance Coverage Provided)		
For delivery information visit our website at <a href="http://www.usps.com">www.usps.com</a>		
71791000114916897354 NASHVILLE TN 37243		
Postage	\$ 0.46	\$0.46
Certified Fee	\$3.10	\$3.10
Return Receipt Fee (Endorsement Required)	\$2.55	\$2.55
Restricted Delivery Fee (Endorsement Required)	\$0.00	\$0.00
Total Postage & Fees	\$ 6.11	\$6.11
Sent To Rep. James (Micah) Van Huss 301 6th Avenue North Suite 23 Legislative Plaza Nashville, TN 37243 Street, Apt. No.; or PO Box No. City, State, Zip+4		
PS Form 3800, August 2006 See Reverse for Instructions		



Code: TCH/Van Huss

SUPPLEMENTAL- # 1

March 25, 2013

12:15pm

<b>CERTIFIED MAIL™ RECEIPT</b> (Domestic Mail Only; No Insurance Coverage Provided)			
For delivery information visit our website at <a href="http://www.usps.com">www.usps.com</a>			
71291000164916897538 JOHNSON CITY TN 37601			
Postage	\$ 0.46	\$0	\$5
Certified Fee	\$3.10	\$3	10
Return Receipt Fee (Endorsement Required)	\$2.55	\$2	00
Restricted Delivery Fee (Endorsement Required)	\$0.00	\$0	00
<b>Total Postage &amp; Fees</b>	<b>\$ \$6.11</b>	<b>\$6</b>	<b>11</b>
<p><b>Sent To</b> Mayor Jeff Banyas Municipal &amp; Safety Building 601 E. Main Street Johnson City, TN 37601</p> <p><b>Street, Apt. No., or PO Box No.</b></p> <p><b>City, State, Zip+4</b></p>			
<b>PS Form 3800, August 2006</b> <b>See Reverse for Instructions</b>			



Code: TCH/Banyas

**SUPPLEMENTAL- # 1**  
**March 25, 2013**  
**12:15pm**



CERTIFIED MAIL™ RECEIPT		
(Domestic Mail Only; No Insurance Coverage Provided)		
For delivery information visit our website at <a href="http://www.usps.com">www.usps.com</a>		
JONESBOROUGH, TN 37659		
71 1000164415077567		
Postage	\$0.46	
Certified Fee	\$3.10	
Return Receipt Fee (Endorsement Required)	\$2.55	
Restricted Delivery Fee (Endorsement Required)	\$0.00	
Total Postage & Fees	\$6.11	
Sent To: Mayor Dan Eldridge Washington County Mayor's Office Street, Apt. No., or PO Box No.: 103 W. Main Street City, State, Zip+4: Jonesborough, TN 37659		
PS Form 3800, August 2006 See Reverse for Instructions		



Code: TCH/Eldridge

**SUPPLEMENTAL- # 1**  
 March 25, 2013  
 12:15pm

<b>CERTIFIED MAIL™ RECEIPT</b> (Domestic Mail Only; No Insurance Coverage Provided)			
For delivery information visit our website at <a href="http://www.usps.com">www.usps.com</a>			
71791080364816897422 NASHVILLE TN 37243			
Postage	\$	\$0.46	\$0.46
Certified Fee		\$3.10	\$3.10
Return Receipt Fee (Endorsement Required)		\$2.55	\$2.55
Restricted Delivery Fee (Endorsement Required)		\$0.00	\$0.00
<b>Total Postage &amp; Fees</b>	<b>\$</b>	<b>\$6.11</b>	<b>\$6.11</b>
<b>Sent To</b>		<b>Senator Rusty Crowe</b> 301 6th Avenue North Suite 8 Legislative Plaza Nashville, TN 37243	
<b>Street, Apt. No., or PO Box No.</b>			
<b>City, State, Zip+4</b>			
<b>PS Form 3800, August 2006</b> <b>See Reverse for Instructions</b>			



Code: TCH/Crowe

**SUPPLEMENTAL- # 1**  
**March 25, 2013**  
**12:15pm**

Certified Number	Sender	Recipient	Date Mailed	Delivery Status
71791000164916897354		Rep. James (Micah) Van Huss, 301 6th Avenue North, Suite 23 Legislative Plaza, Nashville, TN, 37243 Code: TCH/Van Huss	2/28/2013	Delivered March 07, 2013 GREEN CARD SIGNED
71791000164916897422		Senator Rusty Crowe, 301 6th Avenue North, Suite 8 Legislative Plaza, Nashville, TN, 37243 Code: TCH/Crowe	2/28/2013	Delivered March 07, 2013 GREEN CARD SIGNED
71791000164916897538		Mayor Jeff Banyas, Municipal & Safety Building, 601 E. Main Street, Johnson City, TN, 37601 Code: TCH/Banyas	2/28/2013	Delivered March 08, 2013 GREEN CARD SIGNED
71791000164916897569		Mayor Dan Eldridge, Washington County Mayor's Office, 103 W. Main Street, Jonesborough, TN, 37659 Code: TCH/Eldridge	2/28/2013	Delivered March 08, 2013 GREEN CARD SIGNED

# ARTICLES

AFFIDAVIT

2013 MAR 25 PM 12 10

STATE OF GEORGIA

COUNTY OF FULTON

NAME OF FACILITY: TRI-CITIES HOLDINGS LLC  
4 WESLEY COURT  
JOHNSON CITY, TENNESSEE

I, STEVE KESTER, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Steve W. Kester / MANAGER  
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 25 day of March, 2013  
witness my hand at office in the County of Fulton, State of Georgia.

Theresa P. L. L. L.  
NOTARY PUBLIC

My commission expires 03/27/14

HF-0043

Revised 7/02

# COPY- SUPPLEMENTAL-2

Tri-Cities Holdings, LLC

CN1303-005

Law Offices  
James A. Dunlap Jr. & Associates LLC  
801 West Conway Drive NW  
Atlanta, Georgia 30327

**SUPPLEMENTAL- # 2**

March 28, 2013

9:00 am

Phone: (404) 354-2363

Fax: (404) 745-0195

2013 MAR 23 AM 9:02

E-mail:

jim@jamesdunlaplaw.com

March 27, 2013

VIA FEDERAL EXPRESS

Phillip Earhart  
Tennessee Health Services And Development Agency  
Frost Building, 3rd Floor  
161 Rosa L. Parks Boulevard  
Nashville, TN 37243

Re: **Application for Certificate of Need**  
**Applicant: Tri-Cities Holdings LLC**

Dear Phillip:

Please find enclosed an original and two copies supplement information for the Application for Certificate of Need by Tri-Cities Holdings LLC.

Please contact me if you have any questions or if I may be of assistance.

Sincerely,  
James A. Dunlap Jr. & Associates LLC



James A. Dunlap Jr.

JAD/jd  
Enclosures



March 28, 2013

9:00 am

132

Tri Cities Holdings, LLC  
 6555 Sugarloaf Parkway  
 Suite 307-137  
 Duluth, GA 30097  
 404-664-2616

2013 MAR 28 AM 9:02

March 27, 2013

Phillip Earhart  
 Health Services Development Examiner  
 Health Services & Development Agency  
 161 Rosa Parks Boulevard  
 Nashville, TN 37203

RE: Certificate of Need Application CN1303-005  
 Tri-Cities Holdings, LLC

Dear Mr. Earhart:

Thank you for reviewing our revised application and we are pleased to respond to your remaining questions.

We have listed your questions in **bold** and typed our response immediately following. We have also included the following attachments:

- Revised Page 22
- Project Costs Chart (should go after page 29, and be page numbered 29A)
- Revised Financial Resources documentation, should replace pages 113 and 114 and again on pages 116 and 117
- Projected Data Chart (confirms pages 30, 31 and 32; page 36 should be deleted)
- Executed Affidavit

**1. Section A, Applicant Profile, Item 6**

**TennCare covers the drug buprenorphine for treatment of opiate addiction. The medication, medical services and transportation to providers are a covered TennCare benefit. With this in mind, please clarify the reason why you are not planning to accept TennCare for suboxone patients. What incentive does a TennCare patient have to come to the proposed clinic to receive buprenorphine when their medications and transportation services may be paid by TennCare by going to a private provider who prescribes suboxone who is already located in the proposed service area?**

**Response:** None of the 12 opiate treatment programs in Tennessee currently accept TennCare based on a 3/25/2013 telephone survey. The Applicant is not planning on accepting TennCare for the following reasons:

- The investment in personnel and systems, the on-going compliance and audit requirements, and the risk of penalties for non-compliance do not warrant the added revenue
- Based on the Applicant's experience, there are additional risks associated with comingling TennCare patients with self-pay patients (arguments, humiliation, etc.) such that is not worth implementing TennCare

Pertaining to the reasons a patient would chose our facility over a private provider, the Applicant states:

- Most private providers are general family practices and do not have the expertise or focus our program would offer.
- Most private providers do not offer early morning hours that accommodate work, school and family obligations.
- Most private providers do not offer counseling or group meetings in their office, which our program would offer.
- Most private providers do not drug test, implement drug diversion control, test for HIV, TB, etc., which our program would offer.

However, if a private provider provided the services, hours and operation, and expertise listed above, and accepted TennCare, a TennCare patient seeking buprenorphine treatment would have no reason to use our facility.

## **2. Section A, Applicant Profile, Item 12.**

**Please clarify if methadone treatment is offered as part of the TennCare benefit package for patients ages 18-20 years of age. The response in the first supplemental response was unclear.**

**Response:** Applicant sources the following quotation from TennCare Quick Guide May 2012, p. 9 and 12.

*"Methadone Clinic Services – Not Covered, except for children under age 21. [Rules 1200-13-13-.04, 1200-13-14-.10, 1200-13-14-.04, & 1200-13-14-.10]."*

Source: TennCare Quick Guide May 2012, p. 9

(<http://www.tn.gov/tenncare/forms/quickguide.pdf>). This indicates that methadone treatment and buprenorphine is covered for 18-20 year olds.

*"Pharmacy Non-Covered Items. The following items are Not Covered, except for children under age 21 or as otherwise noted below..."*

*"Generic buprenorphine, Subutex (buprenorphine), and Suboxone (buprenorphine/naloxone) in dosage amounts that exceed sixteen milligrams (16 mg) per day for a period of up to six months (which for a pregnant enrollee shall not begin until the enrollee is no longer pregnant), or eight milligrams (8 mg) per day at the end of a six-month period."*

Source: TennCare Quick Guide May 2012, p. 12

(<http://www.tn.gov/tenncare/forms/quickguide.pdf>).

**The applicant stated in the supplemental response "applicant will provide documentation to allow patients to make claims to TennCare". Please discuss this process.**

**Response:** Applicant placed another call to TennCare Solutions at 1-800-878-3192. The representative confirmed that out-of-network claims may be reimbursable. The process explained to the Applicant was that the TennCare member would call this number, answer some questions from TennCare Solutions, and a reimbursement amount, if any, would be determined. The TennCare member would then be given instructions by TennCare Solutions to submit the claim for reimbursement, subject to review by TennCare Solutions. Applicant will provide a sales receipt for all medication and services to allow patients to submit a claim to TennCare but this will be up to the patient to make any and all claims—if in fact reimbursement is available. Applicant will not

offer any warranty or representation about TennCare coverage as to any item of service or medication. Applicant does not intend to make claims on behalf of any patient to TennCare.

### 3. Section B, Project Description, Item 1

**Public Chapter 363 of the Acts of the 2001 General Assembly Methadone Treatment Facilities created Methadone Service Areas (MSAs) on the assumption the closer one lives to a treatment program, the greater likelihood of participation. The rate of participation is nearly twice as high for those living in or near a county that houses a methadone program (59.0/100,000) than the rate for those that live 60 miles or more from a program (32.2/100,000). Please indicate if all population of the proposed service area lives within 60 miles of the proposed project location. If not, what is the percentage that does?**

**Response:** Applicant estimates that 90% of the proposed service area's population is within 60 miles based on using Google directions and the shortest time driving option. The calculations and assumptions are shown below.

Demographic	Population, 2011 estimate	Estimated % within 60 miles	Population within 60 miles	Comment
Sullivan	157,419	100%	157,419	Entire county is within 60 miles
Washington	124,353	100%	124,353	Entire county is within 60 miles
Greene	69,339	100%	69,339	Entire county is within 60 miles
Hamblen	63,062	58%	36,786	Half of Morristown and areas northeast are less than 60 miles
Carter	57,185	100%	57,185	Entire county is within 60 miles
Hawkins	56,671	98%	55,538	Only the lowest southwest portion of the county is greater than 60 miles
Cocke	35,544	10%	3,554	Small population off of exit 12 on I81 is less than 60 miles
Unicoi	18,280	100%	18,280	Entire county is within 60 miles
Johnson	18,231	100%	18,231	Entire county is within 60 miles
Total for service area	600,084	90%	540,685	

The applicant was requested to contact the Department of Mental Health Methadone Authority, Attention Ira Lacey (615-552-7802) to discuss how the

**applicant's plans will interact with the DMHDD Methadone Authority's statewide plan. Did the applicant make contact, and if so, please discuss.** 9:00 am

**Response:** The Applicant talked to Mr. Ira Lacy on March 27, 2013. Mr. Lacy understands our position that the opiate abuse and addiction issues in northeast Tennessee warrant attention, and he confirmed there was no comparable treatment in the proposed service area to the treatment services we are proposing. Mr. Lacy explained the licensing and Central Registry procedures.

Further, Applicant's Managing Member had a substantive meeting on March 25, 2013 with the following representatives from the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS): Commissioner Doug Varney, Deputy Commissioner Marie Williams, Director of Licensure Cynthia Tyler, and Director of Legislation Kurt Hippel.

Applicant characterizes the meeting as very positive and potential grounds of agreement were as follows:

- The severe problems of opiate abuse in Tennessee and the proposed service area
- That no opiate treatment programs exist in the proposed service area and many adults drive great distances to get these treatment services in Asheville, Knoxville, Boone, NC and Galax, VA
- Distance is a barrier to treatment
- Applicant's Manager shared his history with proposed treatment services and the vision of TCH to implement these services in the proposed service area.

**The scheduled hours of 5:00 AM until noon seven days per week is noted on page 98 of the application. However, on page 109 the Johnson City Zoning Regulations for methadone facilities states "the hours of operation shall be between 7:00 a.m. and 8:00 p.m." Please clarify.**

**Response:** Applicant has requested a zoning variance from Johnson City to accommodate these hours.

**Also, the Johnson City Zoning Regulations states, "the facility shall be located on and primary access shall be from an arterial street." How does the applicant intend to address this zoning regulation while the proposed site is located on a cul-de-sac?**

**Response:** Applicant has requested Johnson City grant the Board of Zoning Appeals the authority to grant this arterial road variance. Applicant looked at over 50 sites within the Tri-Cities area and felt that the proposed site best met the needs of the community and patients relative to patient access, traffic, visibility, and distance from schools, daycare, parks.

**The types of businesses that surround the proposed methadone project are noted. Are these businesses in support of the proposed project?**

**Response:** There are two other businesses located on Wesley Court, CK Supply and Thomas Construction, both related to construction. Applicant contacted and briefed the landlord/owner of one of the business and this individual voiced no opposition. The landlord of Applicant's proposed property knows the owner/landlord of the other business and has briefed that individual, and this individual has voiced no opposition to date. The Applicant would characterize their responses as neutral.



**The size and capacity of the parking lot consisting of 68 spaces is noted. Please clarify if the applicant already owns the space to add 100 parking spaces and street level parking.**

**Response:** The combined parking between 68 on-site which are owned by applicant's landlord can be supplemented at least 12 spaces on the property that can simply have lines painted for standard parking spaces (two on the south side of the building, and ten on the north side. This would make a total of 80 spaces. There are an estimated additional 20 unmarked spaces in front and back of the facility that is on property owned by applicant's landlord. Applicant's ratio of patients to parking spaces after year two would still remain below the ratio of several other existing Tennessee OTPs as shown below.

Tennessee Treatment Program	Patients <sup>1</sup>	Parking spots	Parking spots per patient
Hamilton Co./Volunteer	1963	80	24.5
Davidson Co./Middle Tenn	1789	89	20.1
DRD Knoxville	1063	70	15.2
<b>TCH Johnson City – End of Year 2</b>	<b>1208</b>	<b>80</b>	<b>15.1</b>
Solutions of Savannah	545	46	11.8
<b>TCH Johnson City – End of Year 1</b>	<b>918</b>	<b>80</b>	<b>11.4</b>
DRD Knoxville Central	1035	97	10.7
Jackson Professional Associates	795	102	7.8
Shelby Memphis	741	110	6.7
Shelby Co./ADC	408	75	5.4
Shelby Raleigh	326	60	5.4
Dyer Co.Midsouth	224	50	4.5

**What is the timeframe for this project and proposed cost? Is this cost included in the projected data chart?**

The Applicant does not feel parking will be an issue, and no costs are reflected in the Projected Data Chart to remedy a parking problem.

**4. Section C, Need, Item 1. (Service Specific Criteria-Any)**

Please respond to the section labeled "Relationship to Existing Applicable Plans" in *Tennessee's Health: Guidelines for Growth, Criteria and Standards for Certificate of Need, 2000 Edition*: Non- Residential Methadone Treatment Facilities, Criteria and Standards. Please list each criterion separately and provide a response to each criterion separately immediately following the criterion statement, stating how the proposed project will address/relate to each criterion.

**On page 20 of the application the applicant estimates the economic savings to the State to be \$765 per patient per month based on studies in the states of Washington and Tennessee. This study appears to only pertain to Medicaid patients. Did the applicant apply this study to all patients? Please clarify, expand and discuss.**

<sup>1</sup> Note: 2008 Tennessee Registry Data

**Response:** Applicant estimates that 30%-50% of patients are Medicaid-eligible based on the populations at other clinics in which Applicant's Manager is a part owner. This would reduce the total cited on Page 20 accordingly. However, in the report "*Prescription Drug Abuse In Tennessee*" conducted by the Tennessee Department of Health, the study states that the State-funded costs of children of parents who are substance abusers entering state custody and juvenile justice State custody total \$57 million annually. This figure includes all substance abuse, not just opiates, but a) opioid have become the #1 abused drug (as measured by treatment admissions) and has also passed alcohol and b) this does not include any State-funded adult medical costs<sup>2</sup>.

**The applicant refers to Attachment C1-A, Tennessee Methadone Service Areas" in responding to service area specific criteria on page 22 of the application. The attachment the applicant is referring to is Attachment C.3. Please revise and submit a revised page 22.**

**Response:** Applicant apologizes for the oversight. See Attachment Revised Page 22, with the correct reference.

**5. Section C, Economic Feasibility, Item 1 (Project Costs Chart)**

**The applicant did not resubmit a Project Costs Chart for the revised supplemental submission. Please submit.**

**Response:** Applicant apologizes for the oversight. See Attachment Project Costs Chart, which should go after page 29, and be page numbered 29A

**6. Section C, Economic Feasibility, Item 2**

**A fax under separate cover documenting financial resources is noted. However, for appropriate documentation please provide a letter from a banking institution, Certified Public Account, etc. that demonstrates financial resources and/or reserves to implement the proposed project.**

**Response:** Applicant submits Attachment Revised Financial Resources from the brokerage account under the control of the Applicant's Manager for purposes of financially securing this project.

**7. Section C, Economic Feasibility, Item 4 (Projected Data Chart)**

**There are two Projected Data Charts with two different financial outcomes in Year Two of the proposed project. Please submit the Projected Data Chart (that includes management fee fields) the applicant intends to attach to this proposed project.**

**Response:** Applicant apologizes for placing the previous Projected Data Chart in the document in addition to the revised Projected Data Chart. See Attachment Projected Data Chart for the correct Projected Data Chart. The previous Projected Data Chart (page 36) can be deleted.

**8. Orderly Development Item 1**

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[http://tn.gov/mental/policy/persec\\_drug\\_docs/Prescription%20Drug%20Use%20in%20TN\\_2%203%202012\\_R2.pdf](http://tn.gov/mental/policy/persec_drug_docs/Prescription%20Drug%20Use%20in%20TN_2%203%202012_R2.pdf)

**The applicant states, "because of the epidemic levels of prescription medication abuse, Tennessee providers have experienced increases in enrollment." Please provide statistics to back this statement.**

**Response:** *"The Centers for Disease Control and Prevention has classified prescription drug abuse as an epidemic".<sup>3</sup>* In the Tennessee Department of Health report entitled *"Prescription Drug Abuse In Tennessee"*, on page 14, Tennessee indicates that opioid abuse in Tennessee is materially higher than in the United States, as measured by primary drug abused. Further, the National Survey on Drug Use and Health, 2007-2008 states *"In 2007-2008, Tennessee ranked first among all states for past-year non-medical use of pain relievers among persons age 26 or older."* on page 1.<sup>4</sup> On page 2, the same report shows a map of the United States and Tennessee is color-coded with the highest percentage of non-medical use of prescription pain relievers. The Applicant contends that if the CDC indicates the problem is an epidemic in the United States, and if Tennessee ranks first among all states in abuse, it is an epidemic in Tennessee.

#### **9. Section C, Orderly Development, Item 6.B**

**The applicant's methadone fee of \$10.00 per day appears to be considerably less than other surveyed clinics amounts of \$11-\$13, \$16.14 and \$25.00. Please clarify.**

**Response:** This information is correct. Applicant sees tremendous benefit to lowering the barriers to treatment, and cost is a major factor. The Applicant's intent is to offer this rate for a time of 6 months to two years, depending on patient census. In the Applicant's Manager's other clinics in which he owns a partial interest, these clinics had tremendous results "getting the word out" and breaking down barrier to treatment by offering treatment for \$1 per day for periods of six months to over a year.

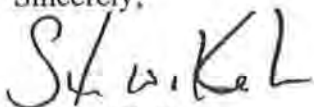
#### **10. Notification Requirements**

**Please provide a copy of each signed certified mail delivery green card that was sent to public officials in accordance to Tennessee Code Annotated 68-11-1607(c)(3).**

**Response:** The letters to all required persons were sent on or about March 5, 2013 and shown on page 131. The letters were received as shown in the electronic receipt provided on page 136 with tracking numbers. Applicant's attorney used LaserSubstrates, a web-based service to print and track certified letters (<https://www.printcertifiedmail.com>). The Green Cards have not been returned by the Postal Service yet.

Also included is our signed Affidavit.

Sincerely,



Steven W. Kester  
Managing Member  
Tri Cities Holdings, LLC

<sup>3</sup> Direct quote from: <http://www.whitehouse.gov/ondcp/prescription-drug-abuse>

<sup>4</sup> [http://www.whitehouse.gov/sites/default/files/docs/state\\_profile\\_-\\_tennessee.pdf](http://www.whitehouse.gov/sites/default/files/docs/state_profile_-_tennessee.pdf)



AFFIDAVIT

2013 MAR 28 AM 9:02

STATE OF GEORGIA

COUNTY OF GWINNETT

NAME OF FACILITY: TRI CITIES HOLDINGS LLC

I, STEVEN W. KESTER, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

St. W. Kester  
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 27 day of March, 2013, witness my hand at office in the County of Gwinnett, State of Georgia.

Jake Matson  
NOTARY PUBLIC

My commission expires Jan. 4, 2016.

HF-0043

Revised 7/02



**Response to  
Public Chapter 363  
of the  
Acts of the 2001 General Assembly**

**Methadone Treatment Facilities**

**Report prepared by**

**Tennessee Department of Health  
in Consultation with the  
Methadone Task Force,  
Health Care Facilities Commission and  
Board for Licensing Health Care Facilities**

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## SCOPE OF REPORT

Due to the increased attention in the placement of methadone treatment facilities and the need for these facilities, the General Assembly charged the Commissioner of Health to conduct a study of methadone treatment facilities and report back to the House Health and Human Resources Committee and the Senate General Welfare, Health and Human Resources Committee on or before January 1, 2002.

Public Chapter 363 of the Acts of the 2001 General Assembly directs the Commissioner of Health to study issues relating to the need for and location of non-residential treatment facilities in the Certificate of Need process in consultation with the Health Facilities Commission and the Board for Licensing Health Care Facilities.

This report will contain reviews conducted of current federal and state regulations of methadone treatment facilities, state oversight of Tennessee facilities, literature on national concerns, regulations from other states, and reports from the Tennessee Board of Pharmacy.

To the extent possible, recommendations will be based on a thorough review of all data, nationally accepted facts, and practice standards of methadone facilities.

This report includes recommendations to current regulations utilized by state survey agencies and *Guidelines for Growth* used by the Health Facilities Commission in making decisions about need.

## REPORT PROCESS

This study was conducted in monthly meetings with committee members being appointed by the Commissioner of Health. Monthly meetings were conducted on September 27, 2001, October 23, 2001, November 13, 2001, and December 18, 2001. A membership list is attached in the exhibits.

Task force members and Health Facilities Commission members were given an opportunity to review the draft report in order to make comments and suggestions prior to finalizing the report.

Some members expressed concerns about the proposed rule changes dealing with:

- 1) Observed testing and
- 2) Diversion Control Plan

These comments are attached in exhibits. (Note: Exhibits are not available for downloading.)

## BACKGROUND

### National Concerns

The November 1997 *National Institutes of Health Consensus Statement, Effective Medical Treatment of Opiate Addiction* estimated that only 115,000 of the total 600,000 estimated opiate-dependent persons in the U.S. were in methadone maintenance treatment (MMT) programs. The Consensus Statement reported that, "MMT is effective in reducing illicit opiate drug use, in reducing crime, in enhancing social productivity, and in reducing the spread of viral diseases such as AIDS and hepatitis." Although a totally drug-free state would be preferable, most opiate-dependent persons, according to research, cannot achieve and maintain this worthy target. MMT, as a substitute for a drug-free state, does reduce drug use, decrease criminal activity, provide an opportunity for employment and significantly improve quality of life for patients.

Opiate use has clear and well-defined health, employment and criminal consequences according to the Consensus Statement. The total financial costs of untreated opiate dependence to the individual, family and society was estimated at \$20 billion by the NIH in its Consensus Statement. Numerous studies throughout the world have demonstrated that participation in MMT leads to significant reductions of illegal opiate use as well as other illicit drugs.

The mortality rate for opiate-dependent persons in methadone treatment programs is 30% of the mortality rate for those not participating in treatment. Persons who are not participating in MMT have higher incidence rates of bacterial infections, tuberculosis, hepatitis B and C, AIDS and other sexually transmitted diseases and alcohol abuse. Health care costs alone were estimated in the 1997 Consensus Statement to amount to \$1.2 billion for opiate dependence.

Opiate use has an adverse impact upon employment and an individual's contribution to society. Since users spend an inordinate amount of time in finding and taking the drug, maintaining employment is often difficult. Many users look to public assistance to support themselves and their families. Studies have demonstrated, however, that MMT patients earn incomes that are double those of opiate users not in treatment.

Opiate use often leads users to criminal behavior. Stealing is the most common offense. The Consensus Statement reports that more than 95% of opiate users reported committing crimes in span of an 11-year period when they were using opiates. Numerous studies have demonstrated that "effective treatment of opiate dependence markedly reduces the rates of criminal activity."

Many persons associate dependency solely on heroin use. Too often, legally prescribed controlled substances, including opiates such as hydrocodone and morphine, are diverted for illegal use. In fact, the February 2001 edition of the *Psychiatric Times* reported that a national Substance Abuse and Mental Health Services Administration (SAMHSA) survey indicated that approximately 3.9 million Americans currently use prescription-type psychotherapeutic drugs for nonmedical reasons, almost twice as many as the 2.1 million who use heroin, cocaine and/or crack cocaine.

The NIH Consensus Statement addresses many of the misconceptions and stigmas associated with opiate dependence and methadone treatment programs. NIH urges that “vigorous and effective leadership is needed to inform the public that dependence is a **medical disorder** (emphasis added) that can be effectively treated with significant benefits for the patient and society.”

### Tennessee Problems

No public health data exist which accurately depicts the extent or severity of opiate addiction in Tennessee. Extrapolating the NIH estimates to Tennessee provides as reasonable an approach as any, resulting in estimates that 12,000 or more Tennesseans are opiate dependent. In December 2001, less than 3,000 persons were actively participating in non-residential treatment programs in the state which represents only a fraction of the state’s estimated opiate users.

Generally, the closer one lives to a treatment program, the greater likelihood of participation. The current rate of participation is nearly twice as high for persons living in or close to one of the five counties (Shelby, Davidson, Knox, Hamilton and Madison) that house programs, 59.0/100,000 than the rate for those that live 60 miles or more from a program, 32.2/100,000.

The relatively few number of programs in the state that are available to opiate-dependent persons also contributes to low participation rates. Although the number of programs in other Southeastern states varies widely, Tennessee’s six programs yields a rate of just 1.1 programs/one million population, less than one-half the 2.4/one million rate of the other states.

As is true around the country, substance abuse probably cannot be attributed solely to illegal substances in this state. Although Tennessee does not maintain a system for capturing data on the number of prescriptions filled, vendors in Tennessee cite the state as one of the top five in the country for purchase of Hydrocodone, Cocaine and Meperidine, all controlled substances that are easily diverted for illegal use.

### Tennessee Regulatory Oversight

Tennessee Code Annotated requires that a vendor wanting to open a methadone treatment program must first receive a Certificate of Need from the Tennessee Health Facilities Commission and then be licensed by the Department of Health as a non-residential methadone treatment facility. Unfortunately, the *Guidelines for Growth* that have been developed do not provide concrete, objective criteria that can be used to adequately determine the appropriateness of awarding a Certificate of Need.

The regulatory oversight of Methadone Treatment Facilities began in 1988 by the Tennessee Department of Mental Health. In March, 1994 that oversight was transferred to the Department of Health, Health Care Facilities. Rules and regulation were amended by the Department in August, 1999 with encouragement and support of the General Assembly.



Currently there are 6 clinics operating in Tennessee in the following counties: Shelby, Davidson, Knox, Hamilton and Madison. Each clinic is surveyed annually and as necessary when complaints are filed.

For the past 2 years an average of 2 deficiencies have been sited per survey and consist of:

- No Individual Treatment Record
- Client history and treatment plans not reviewed every 90 days
- No documentation of staff training for STD/HIV Training
- Admission screening test not done – TB test, and pregnancy test for females
- No annual justification for continued treatment
- No evidence of annual physical
- Urine drug screens not conducted on new clients
- No physician's signature on medication order changes

There have been 3 complaints filed in the past two years.

## FINDINGS OF FACT

During the review of the vast amount of materials and interviewing of individuals, the following facts were formulated and agreed upon by the panel:

- ❖ Businesses that establish programs require a general population of at least 100,000 persons from which to draw potential clients. This figure is believed to generate 67 clients on average. Private businesses normally will not establish a program unless a minimum caseload of 60 patients is available.
- ❖ The closer one lives to a treatment program, the greater likelihood of participation as based on current participation in Tennessee Methadone Treatment facilities—
  - 59.0/100,000 population participate in programs 60 miles or less
  - 32.2/100,000 population participate in programs over 60 miles
- ❖ The NIH Consensus Statement of November, 1997 estimated that only 115,000 of the total 600,000 estimated opiate-dependent persons in the U.S. were in methadone maintenance treatment programs.
- ❖ Applying the NIH 1997 Consensus statement estimates of approximately 20% of opiate-dependent persons to Tennessee Census data, the number of potential clients could be as high as 12,300 within the state indicating only a fraction of the opiate users in the state are currently participating in methadone treatment programs.
- ❖ The financial costs of untreated opiate dependence to the individual, family and society was estimated at \$20 billion by the NIH in its Consensus Statement.
- ❖ Opiate use has clear and well-defined health consequences. The mortality rate for opiate-dependent persons in methadone treatment programs is 30% lower than for dependent persons not participating in treatment. Numerous studies have demonstrated that participation in methadone maintenance treatment programs (MMT) leads to significant reductions of illegal opiate use as well as other illicit drugs.
- ❖ Since no data exists otherwise, it was presumed that the prevalence of opium-dependence was similar throughout the state.
- ❖ From a public policy standpoint, placing persons in a nonresidential methadone treatment program is preferable than allowing persons to remain addicted to heroin or other opiates.
- ❖ All Tennesseans who are eligible for and choose to participate in nonresidential methadone treatment should have reasonable geographic access to a program.
- ❖ Access should allow participants to develop a life that could include full employment and meaningful contributions to society.

- ❖ The number of reported methadone treatment facilities per SAMHSA in neighboring states varies widely:

<u>STATE</u>	<u>#</u>	<u>Rate/one million population</u>
Alabama	17	3.8
Arkansas	3	1.1
Georgia	24	2.9
Kentucky	15	3.7
Mississippi	2	.7
Missouri	12	2.1
North Carolina	18	2.7
Tennessee	6	1.1
Virginia	14	2.3

## SUMMARY

In response to Public Chapter 363 of the Acts of 2001, the Commissioner of Health assembled a Methadone Task Force comprised of persons interested and involved in the subject of Methadone Maintenance Treatment (MMT). This task force held several meetings between September 1, 2001 and December 21, 2001 and examined a vast array of information related to Methadone programs, both in Tennessee and throughout the country. Many items that were considered by the group are attached to this report as exhibits.

New federal regulations for MMT were implemented on March 19, 2001. The task force examined the differences in existing Tennessee regulations and the new federal regulations in an effort to determine what changes were needed to the state's regulations for Non Residential Narcotic Treatment Facilities in order to assure compliance and compatibility with the new federal guidelines. In addition to reviewing the new federal regulations, the group reviewed other state regulations for comparison as well. Suggestions and comments were solicited from the methadone industry, methadone treatment specialists and the Department's Bureau of Alcohol and Drug Abuse Services for input on recommendations that would best serve to protect the public health, safety and welfare of the citizens of Tennessee.

Information from the state's Central Registry of Methadone patients in treatment was compiled, analyzed and studied by members of the group. Both the number and participation rate of active patients in treatment per county of residence was determined. Distance was a strong predictor of participation rates. Assuring that all Tennesseans who wish to participate in MMT have reasonable access to a program was used as justification for planning purposes of the proposal to designate 23 Methadone Service Areas (MSA) within the state. An MSA is a county or constellation of contiguous counties in the state that comprise a sufficient general population making it likely that a minimum number of opiate dependent persons reside in the MSA who wish treatment and could support a program. This minimum population foundation was balanced with the need to establish geographic boundaries such that patients living within the MSA would reside within less than an hour drive one-way to a treatment program if the program were established in the heart of the MSA. Refer to exhibit #6 for proposed MSAs.

The Tennessee Board of Pharmacy provided to the panel the DEA's Retail Drug Distribution by Zip Code report for Tennessee. This detailed report showed what prescription drugs were being shipped to various areas of the state. Also provided to the group was the information that revealed Tennessee's ranking in the purchasing of legally prescribed drugs. This report revealed Tennessee in the top five nationally for the purchase of Cocaine, Hydrocodone, and Meperidine (Demerol), each of which can be readily converted to illicit use that contributes to the high rate of opiate dependency in the state.

Although the current Guidelines for Growth were adopted by the Department and the Health Planning Commission in 2001, they still remain vague and lack the specificity as needed to support the philosophy of directing the delivery of health care services for methadone treatment. The group reviewed the current criteria and standards used for assisting the Health Facilities Commission in decisions concerning certificate of need application and felt improvements should be made.

Incorporating the concept of the Methadone Service Areas (MSAs), adding distance in travel time to existing programs and the impact on employment opportunities would strengthen the quality of the information submitted to the Commission when agencies request a Certificate of Need (CON). More comprehensive information would contribute to better decisions relating to need, economic feasibility, and orderly contribution to development of adequate and effective methadone treatment programs and assist the Department and the Health Facilities Commission in determining the appropriateness of issuing a CON.

## RECOMMENDATIONS

As a result of these efforts the Task Force is issuing recommendations within this report relating both to proposed rules changes and changes to the Guidelines for Growth. These recommendations follow in the papers titled "Proposed Rule Amendments to Chapter 1200-8-21 Non-Residential Narcotic Treatment Facilities" and "Guidelines for Growth Proposed Amendments".

*Recommendations of the Methadone Task Force*

December 2001

### Proposed Rule Amendments to Chapter 1200-8-21 Non- Residential Narcotic Treatment Facilities

#### **1200-8-21-.01 Definitions.**

**Recommendation:** Add the following definitions:

1. Counseling Session. Therapeutic discussion between client(s) and a facility counselor for a period of no less than thirty (30) minutes designed to address client addiction issues or coping strategies and treatment plans.

**Rationale:** *Establishes a minimum standard for a counseling session*

2. Observed Testing. Testing conducted and witnessed by a facility staff person to ensure against falsification or tampering of results of a drug screen.

**Rationale:** *Clarification of testing procedure.*

3. Random Testing. Drug screens conducted by the facility that lack a definite pattern of who and when clients are selected for testing; indiscriminate testing.

**Rationale:** *Clarification of current regulatory language.*

4. Relapse. The failure of a client to maintain abstinence from illicit drug use verified through drug screen.

**Rationale:** *To clarify proposed amended language.*

#### **1200-8-21-.02 Licensing Procedures.**

**Recommendation:** Propose amending the following:

1200-8-21-0.2(2)(a). Delete ... "rules of the FDA..." and replace with "...rules of SAMSHA (Substance Abuse and Mental Health Services Administration)..."

**Rationale:** *This change allows Tennessee's regulations to be aligned with those guidelines from the Federal agency, as they have been in the past.*

**1200-8-21-.04 Administration.**

**Recommendation:** Propose amending the following:

1. 1200-8-21-.04(4)(f) Counselors. Delete current language and replace with the following:  
There must be sufficient group and individual counseling available to meet the needs of the client population. At a minimum, the following counseling schedule shall be followed:
  - (i) During 1<sup>st</sup> 90 days of treatment, counseling session(s) shall take place at least one time a week;
  - (ii) During 2<sup>nd</sup> 90 days of treatment, counseling session(s) shall take place at least three (3) times per month;
  - (iii) During the 3<sup>rd</sup> 90 days of treatment, counseling session(s) shall take place at least two (2) times per month;
  - (iv) For subsequent 90 day periods of treatment, counseling session(s) shall take place as needed or indicated in the client's treatment plan, but no less frequent than monthly as long as the client is compliant;
  - (v) If the client experiences a relapse, his/her individualized treatment plan must document evidence of intensified services provided. Such evidence may include, but is not limited to, increase in individual or group counseling session(s) and/or a reduction in the client's take home privileges.

**Rationale:** *A specific counselor to client ratio has proven to be a difficult item to measure and does not dictate the quality of counseling provided. This change is directed at establishing the minimum standard and reflects the Federal change to accreditation rather than regulation. This should allow more flexibility for the clinics to establish quality counseling programs that achieve the desired outcomes necessitated for accreditation.*

2. 1200-8-21-.04(21). Hours of Operation. Propose amending the following:  
Delete the third sentence that states, "In order to accommodate clients who are not receiving take-home medication, facilities must be open for dispensing seven days per week."  
Replace with: Any patient in comprehensive maintenance treatment may receive a single take-home dose for each day that the clinic is closed for business, including Sundays and State and Federal holidays, not to exceed two (2) consecutive days.

**Rationale:** *Would potentially result in improved client compliance and an orderly provision of services.*

3.1200-8-21-.04, (f) 24.

Propose adding the following language:

A Diversion Control Plan shall be in place at each clinic. The Diversion Control Plan must contain, at a minimum, the following:

- (i) The Diversion Control Plan shall apply to all clients receiving take home medication.
- (ii) It will include a random call back program with mandatory compliance. This call back must be in addition to the regular schedule of clinic visits.



- (iii) Each client receiving take-home medications must be called back at a minimum of once per 3 months.
- (iv) Upon call back a client must report to the clinic within 24 hours of notification, with all take home medications. The quantity and integrity of packaging shall be verified. One dose must be replaced and sent for analysis to verify strength and contents.
- (v) The facility shall maintain individual callback results in the client record.
- (vi) The facility must maintain a current log of all callbacks with the results of compliance.

**Rationale:** *Methadone diversion is always a concern both from the clinic standpoint and in the community in which it is located. This rule establishes minimum standards and requires each facility to develop callback plans for diversion control.*

#### **1200-8-21-.05 Admissions, Discharges and Transfers.**

**Recommendation:** Propose to amend the following:

1. 1200-8-21-.05(4)(a) Amend third sentence to read, "Within 72 hours of admission or discharge, the facility shall initiate a clearance inquiry by submitting to the approved central registry the name, date of birth, anticipated date of admission or discharge..."

**Rationale:** *In order for the Central Registry to remain current in information, the SNA must be notified of discharges as well as admissions.*

2. Add the following language: The facility shall ensure that clients are instructed in the proper storage and security of take-home medications after they leave the facility.

**Rationale:** *To provide for the safe storage and handling of take-home medications to protect general welfare of the public.*

#### **1200-8-21-.06 Basic Services.**

1. 1200-8-21-.06(5)(h).

**Recommendation:** Add the following language:

Each clients' individualized treatment plan must include the counseling needs, including both group and individual counseling sessions as indicated by evaluation of the client's length of time in the program, drug screening results, progress notes, and social environment. The treatment plan must be reviewed at least every six (6) months.

2. 1200-8-21-.06(8)(a). Drug Screens. Delete the word Urine.

**Rationale:** *This will allow the use of alternative drug screening at the discretion of the clinic. There are alternative tests available such as saliva and hair that are less invasive for the client, less opportunity for dilution/contamination. Currently they are prohibited from use in Tennessee because this regulation only recognizes urine drug screening*

3. 1200-8-21-.06(9)(c) Take Home Doses. Amend by adding ... "methadone and LAAM"

**Rationale:** *This allows Tennessee regulations to be in conformity with the Federal Regulations.*

#### **4. 1200-8-21-.06 (9) (c )**

**Recommendation:** Propose amending the following:



... “rules of the FDA...” and replace with “...rules of SAMSHA (Substance Abuse and Mental Health Services Administration)...”

**Rationale:** *This change allows Tennessee's regulations to be aligned with those guidelines from the Federal agency, as they have been in the past.*

### **Guidelines for Growth-proposed amendments**

1. Need determinations for non-residential methadone treatment facilities shall strongly consider the Methadone Service Area. [Methadone Service Areas (MSAs) are designated for planning purposes to assist the state agencies in determining the appropriateness of issuing a Certificate of Need. These MSAs were developed in response to assumptions developed by a committee established in response to Public Health Chapter 363 of the Acts of 2001.]

Designation of MSAs was patterned, in concept, after the use of Rational Service Areas by the Department of Health in helping identify underserved health resource shortage areas in Tennessee. An MSA is a county or constellation of contiguous counties in the state that comprise a sufficient general population making it likely that a minimum number of opiate dependent persons reside in the MSA who wish treatment and could support a program. This population foundation was balanced with the need to establish geographic boundaries such that patients living within the MSA would reside within less than an hour drive one-way to a treatment program if it were established in the heart of the MSA. Assumptions that guided determination of MSAs:

- Generally, the closer one lives to a treatment program, the greater likelihood of participation. The rate of participation is nearly twice as high for persons living in or close to one of the five counties that house programs, 59.0/100,000 than the rate for those that live 60 miles or more from a program, 32.2/100,000
- Businesses that establish programs require a general population of no less than 100,000 persons from which to draw potential clients. This figure is believed to generate 67 clients on average. Private businesses normally will not establish a program unless a minimum caseload of 60 patients is available.
- In order to assure a sufficient population base in each MSA to support a treatment program, boundaries of MSAs were drawn to include a general population of 200,000. (Identification of MSAs with less population, e.g. 150,000, led to some areas with barely sufficient population to support a program; more than 200,000 would perpetuate distance barriers to existing programs.)

2. Decisions should be predicated upon improving access to programs that will increase patient compliance and reduce dropout rates and recidivism.

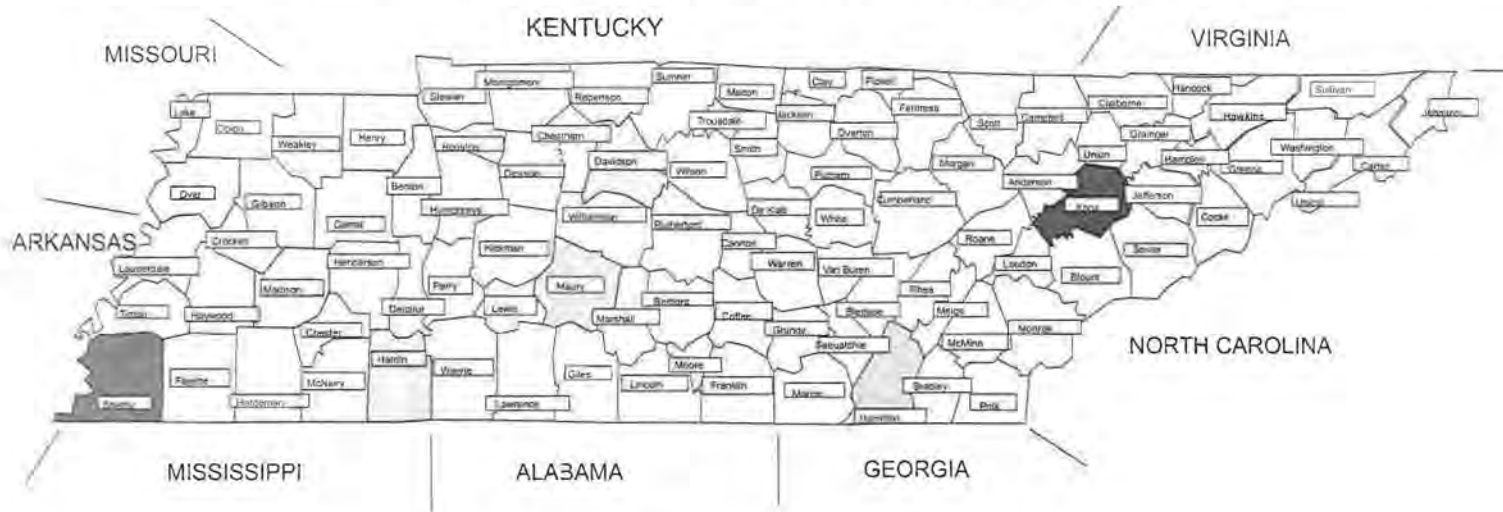
3. Access determinations should include the distance in miles and approximate travel time to the nearest existing programs. Consideration should be given to the quality of life improvements and employment opportunities available if programs were geographically accessible.
4. Strong consideration should be given to an applicant in a multi-county MSA without an existing program if Need, Economic Feasibility and Contribution to Orderly Development are met.
5. Simultaneous review CON applications for programs in the same MSA or a CON application in an MSA where at least one program already exists should demonstrate:
  - Current and potential caseloads
  - Estimated current unmet needs
  - Prospects for long-term viability if multiple programs are approved
  - Experience of the applicant in other locations (in- or out-of-state)
6. The applicant shall provide documentation on any agency in- or out-of-state with which the applicant has legal interest in or is involved in a management role.
7. The Department of Health's application review (TCA 68-11-107) will include recommendations from the State Methadone Authority. Both the Department and the Commission shall consider the State Methadone Authority's quarterly Tracking Report (description of patient census by county of residence).

**Exhibits****(Note: Exhibits are not available for downloading.)**

<b>Exhibit 1</b>	Committee Members
<b>Exhibit 2</b>	Public Chapter 363
<b>Exhibit 3</b>	Non Residential Narcotic Treatment Facility Outcome/Performance Data 1997, 1998, 1999 & 2000
<b>Exhibit 4</b>	Methadone Registry
<b>Exhibit 5</b>	County 2000 Population
<b>Exhibit 6</b>	Possible Methadone Service Areas for NR Methadone Clinic Locations
<b>Exhibit 7</b>	Map
<b>Exhibit 8</b>	Non-Residential Methadone Treatment Facilities (NRMTF)
<b>Exhibit 9</b>	Federal State
<b>Exhibit 10</b>	Chapter 1200-8-21 Rules for Alcohol and Other Drugs of Abuse Non-Residential Narcotic Treatment Facilities
<b>Exhibit 11</b>	Federal Register
<b>Exhibit 12</b>	Retail Drug Distribution
<b>Exhibit 13</b>	1999 Highlights
<b>Exhibit 14</b>	Certificate of Need and Rule Revision Recommendations
<b>Exhibit 15</b>	Volunteer Treatment Center, Inc.

G6022004/BHLR

# Tennessee Opioid Treatment Clinics



○ ONE LOCATION    ● TWO LOCATIONS    ● THREE LOCATIONS

Shelby (Memphis)  
ADC Recovery & Counseling Center  
3041 Getwell, Suite 101  
Memphis, TN 38118  
(901) 375-1050  
Hours of Operation M-F 5a-1:30p; Sat 6a-9a  
Dosing Hours M-F 5:30a-11a; Sat 6a-9a

Memphis Center for Research & Addiction  
1270 Madison Ave  
Memphis, TN 38104  
(901) 722-9420  
Hours of Operation M-F 5:45a-2p; Sat 6a-9a  
Dosing Hours M-F 5:45a-1p; Sat 6a-9a

Raleigh Professional Associates  
2960-B Austin Peay Hwy  
Memphis, TN 38128  
(901) 372-7878  
Hours of Operation M-F 5a-1p; Sat 6a-2p  
Dosing Hours M-F 5a-9a; Sat 6a-10a

Dyer (Dyersburg)  
MidSouth Treatment Center  
640 Hwy 51 Bypass 3, Suite M  
Dyersburg, TN 38024  
(731) 285-6535  
Hours of Operation M-Sat 5a-11a  
Dosing Hours M-F 5a-11a; Sat 6a-10a

Madison (Jackson)  
Jackson Professional Associates  
1869 Hwy 45 Bypass, Suite 5  
Jackson, TN 38305  
(731) 660-0880  
Hours of Operation M-F 5a-1p; Sat 6a-2p  
Dosing Hours M-F 5a-1p; Sat 6a-2p

Henry (Paris)  
Paris Professional Associates  
2555 East Wood Street  
Paris, TN 38242  
(731) 641-4545  
Hours of Operation M-Sat 5a-1p  
Dosing Hours M-Sat 5a-1p

Hardin (Savannah)  
Solutions of Savannah  
85 Harrison Street  
Savannah, TN 38372  
(731) 925-2767  
Hours of Operation M-Sat 5:30a-12p  
Dosing Hours M-F 5:30a-11a; Sat 6a-9a

Maury (Columbia)  
Recovery of Columbia  
1202 South James Campbell Blvd.  
Columbia, TN 38401  
(931) 381-0020  
Hours of Operation M-Sat 5:30a-11a  
Dosing Hours M-F 5:30-11a; Sat 6a-9a

Davidson (Nashville)  
Middle Tennessee Treatment Center  
2410 Charlotte Avenue  
Nashville, TN 37203  
(615) 321-2575  
Hours of Operation M-Sat 6a-1p  
Dosing Hours M-F 6a-1p; Sat 6a-9a

Hamilton (Chattanooga)  
Volunteer Treatment Center, Inc.  
2347 Rossville Blvd  
Chattanooga, TN 37408  
(423) 265-3122  
Hours of Operation M-Sat 5:30a-2p  
Dosing Hours M-F 5:30a-12:30p; Sat 5:30-11a

Knox (Knoxville)  
DRD Knoxville Medical Clinic-Central  
412 Citico Street  
Knoxville, TN 37921  
(865) 522-0661  
Hours of Operation M-Sat 5:30a-2:30p  
Dosing Hours 5:30a-11p; Sat 6a-9a

DRD Knoxville Medical Clinic-Bernard  
626 Bernard Avenue  
Knoxville, TN 37921  
(865) 522-0161  
Hours of Operation M-Sat 5:30a-2:30p  
Dosing Hours M-F 5:30a-11a; Sat 6a-9a

# ARTICLES



Preventing and  
recognizing  
prescription  
drug abuse  
See page 10.

## from the director:

The nonmedical use and abuse of prescription drugs is a serious public health problem in this country. Although most people take prescription medications responsibly, an estimated 52 million people (20 percent of those aged 12 and older) have used prescription drugs for nonmedical reasons at least once in their lifetimes. Young people are strongly represented in this group. In fact, the National Institute on Drug Abuse's (NIDA) Monitoring the Future (MTF) survey found that about 1 in 12 high school seniors reported past-year nonmedical use of the prescription pain reliever Vicodin in 2010, and 1 in 20 reported abusing OxyContin—making these medications among the most commonly abused drugs by adolescents.

The abuse of certain prescription drugs—opioids, central nervous system (CNS) depressants, and stimulants—can lead to a variety of adverse health effects, including addiction. Among those who reported past-year nonmedical use of a prescription drug, nearly 14 percent met criteria for abuse of or dependence on it. The reasons for the high prevalence of prescription drug abuse vary by age, gender, and other factors, but likely include greater availability.

The number of prescriptions for some of these medications has increased dramatically since the early 1990s (see figures, page 2). Moreover, a consumer culture amenable to “taking a pill for what ails you” and the perception of prescription drugs as less harmful than illicit drugs are other likely contributors to the problem. It is an urgent one: unintentional overdose deaths involving opioid pain relievers have quadrupled since 1999, and by 2007, outnumbered those involving heroin and cocaine.

NIDA hopes to change this situation by increasing awareness and promoting additional research on prescription drug abuse. Prescription drug abuse is not a new problem, but one that deserves renewed attention. It is imperative that as a Nation we make ourselves aware of the consequences associated with abuse of these medications.

Nora D. Volkow, M.D.  
Director  
National Institute on Drug Abuse

## Research Report Series

# Prescription Drugs: Abuse and Addiction

## What is prescription drug abuse?

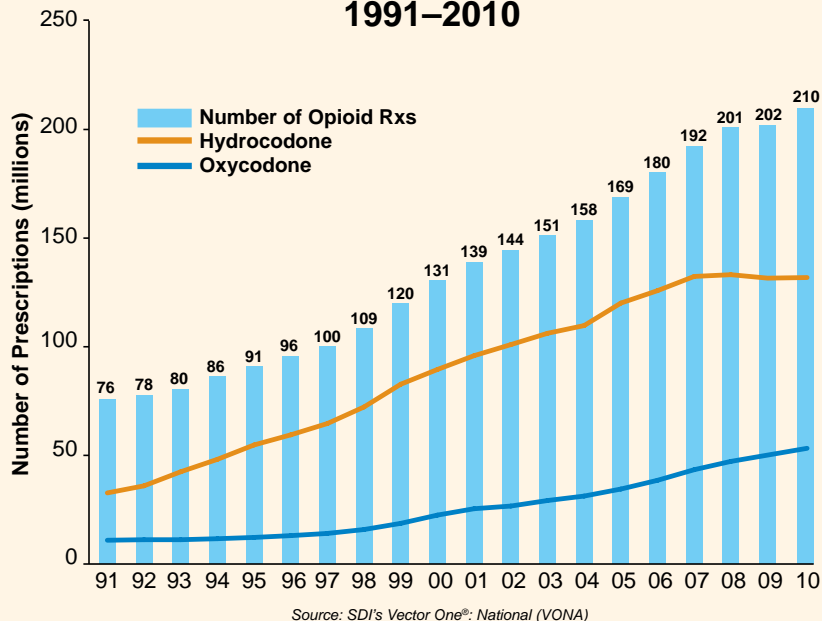
**P**rescription drug abuse<sup>1</sup> is the use of a medication without a prescription, in a way other than as prescribed, or for the experience or feelings elicited. According to several national surveys, prescription medications, such as those used to treat pain, attention deficit disorders, and anxiety, are being abused at a rate second only to marijuana among illicit drug users. The consequences of this abuse have been steadily worsening, reflected in increased treatment admissions, emergency room visits, and overdose deaths.

*continued inside*

<sup>1</sup> Prescription drug abuse, as defined in this report, is equivalent to the term “nonmedical use,” used by many of the national surveys or data collection systems. This definition does not correspond to the definition of abuse/dependence listed in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV).



### Total Number of Opioid Prescriptions Dispensed by U.S. Retail Pharmacies, 1991–2010

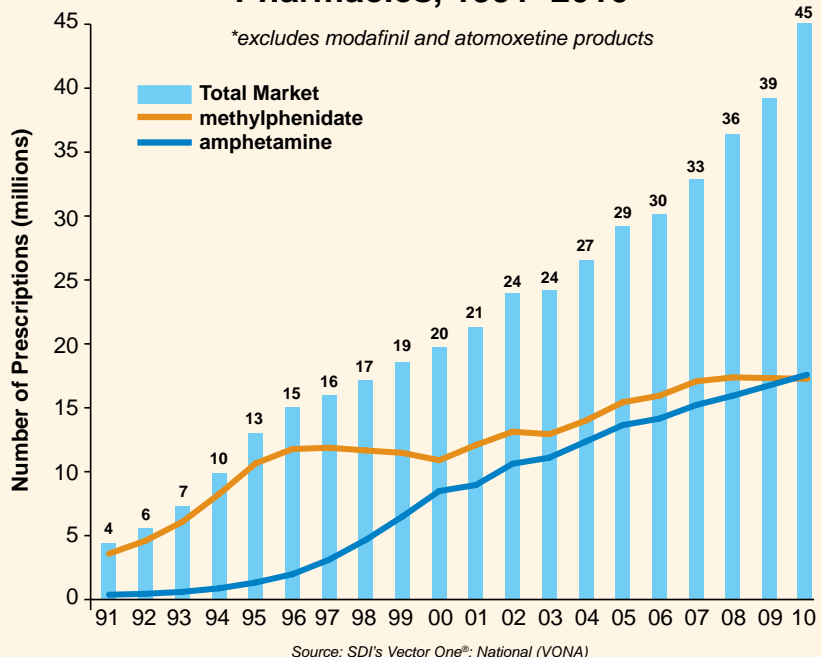


### What are some of the commonly abused prescription drugs?

Although many medications can be abused, the following three classes are most commonly abused:

- Opioids—usually prescribed to treat pain;
- Central nervous system (CNS) depressants—used to treat anxiety and sleep disorders; and
- Stimulants—most often prescribed to treat attention-deficit hyperactivity disorder (ADHD).

### Total Number of Prescriptions for Stimulants\* Dispensed by U.S. Retail Pharmacies, 1991–2010



### Opioids—

#### What are opioids?

Opioids are medications that relieve pain. They reduce the intensity of pain signals reaching the brain and affect those brain areas controlling emotion, which diminishes the effects of a painful stimulus. Medications that fall within this class include hydrocodone (e.g., Vicodin), oxycodone (e.g., OxyContin, Percocet), morphine (e.g., Kadian, Avinza), codeine, and related drugs. Hydrocodone products are the most commonly prescribed for a variety of painful conditions, including dental and injury-related pain. Morphine





is often used before and after surgical procedures to alleviate severe pain. Codeine, on the other hand, is often prescribed for mild pain. In addition to their pain-relieving properties, some of these drugs—codeine and diphenoxylate (Lomotil) for example—can be used to relieve coughs and severe diarrhea.

#### How do opioids affect the brain and body?

Opioids act by attaching to specific proteins called opioid receptors, which are found in the brain, spinal cord, gastrointestinal tract, and other organs in the body. When these drugs attach to their receptors, they reduce the perception of pain. Opioids can also produce drowsiness, mental confusion, nausea, constipation, and, depending

## Dependence vs. Addiction

Physical dependence occurs because of *normal* adaptations to chronic exposure to a drug and is not the same as addiction. Addiction, which can include physical dependence, is distinguished by compulsive drug seeking and use despite sometimes devastating consequences.

Someone who is physically dependent on a medication will experience withdrawal symptoms when use of the drug is abruptly reduced or stopped. These symptoms can be mild or severe (depending on the drug) and can usually be managed medically or avoided by using a slow drug taper.

Dependence is often accompanied by tolerance, or the need to take higher doses of a medication to get the same effect. When tolerance occurs, it can be difficult for a physician to evaluate whether a patient is developing a drug problem, or has a real medical need for higher doses to control their symptoms. For this reason, physicians need to be vigilant and attentive to their patients' symptoms and level of functioning to treat them appropriately.

upon the amount of drug taken, can depress respiration. Some people experience a euphoric response to opioid medications, since these drugs also affect the brain regions involved in reward. Those who abuse opioids may seek to intensify their experience by taking the drug in ways other than those prescribed. For example, OxyContin is an oral medication used to treat moderate to severe pain through a slow, steady release of the opioid. People who abuse OxyContin may snort or inject it,<sup>2</sup> thereby increasing their risk for serious medical complications, including overdose.

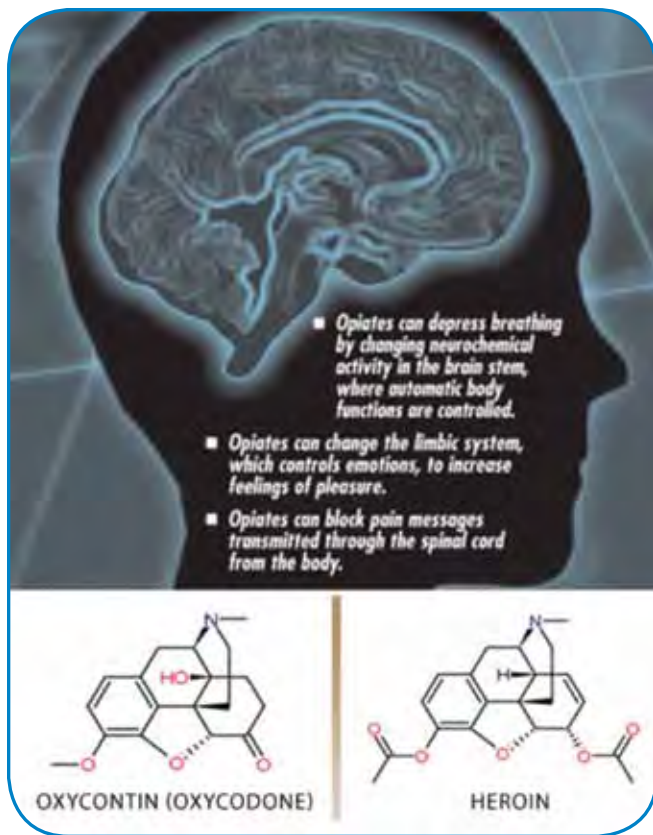
#### What are the possible consequences of opioid use and abuse?

Taken as prescribed, opioids can be used to manage pain safely and effectively. However, when abused, even a single large dose can cause severe respiratory depression and death. Properly managed, short-term medical use of opioid analgesics rarely causes addiction—characterized by compulsive drug seeking and use despite serious adverse consequences. Regular (e.g., several times a day, for several weeks or more) or longer term use or abuse of opioids can lead to physical dependence and, in some cases,



***In 2007, the number of overdose deaths from prescription opioids outnumbered deaths from heroin and cocaine combined.***

<sup>2</sup> Changing the route of administration also contributes to the abuse of other prescription medications, including stimulants, a practice that can lead to serious medical consequences.



*OxyContin and heroin have similar chemical structures and bind to the same receptors in the brain.*

addiction. Physical dependence is a *normal* adaptation to chronic exposure to a drug and is not the same as addiction (see text box on “Dependence vs. Addiction” on page 3). In either case, withdrawal symptoms may occur if drug use

is suddenly reduced or stopped. These symptoms can include restlessness, muscle and bone pain, insomnia, diarrhea, vomiting, cold flashes with goose bumps (“cold turkey”), and involuntary leg movements.

## Over-the-Counter Medicines

Over-the-counter (OTC) medications, such as certain cough suppressants, sleep aids, and antihistamines, can be abused for their psychoactive effects. This typically means taking doses higher than recommended or combining OTC medications with alcohol, or with illicit or prescription drugs. Either practice can have dangerous results, depending on the medications involved. Some contain aspirin or acetaminophen (e.g., Tylenol), which can be toxic to the liver at high doses. Others, when taken for their “hallucinogenic” properties, can cause confusion, psychosis, coma, and even death.

Cough syrups and cold medications are the most commonly abused OTC medications. In 2010, for example, 6.6 percent of high school seniors took cough syrup “to get high.” At high doses, dextromethorphan—a key ingredient found in cough syrup—can act like PCP or ketamine, producing dissociative or out-of-body experiences.

## Is it safe to use opioid drugs with other medications?

Only under a physician’s supervision can opioids be used safely with other drugs. Typically, they should not be used with other substances that depress the CNS, such as alcohol, antihistamines, barbiturates, benzodiazepines, or general anesthetics, because these combinations increase the risk of life-threatening respiratory depression.

## CNS depressants—

### What are CNS depressants?

CNS depressants, sometimes referred to as sedatives and tranquilizers, are substances that can slow brain activity. This property makes them useful for treating anxiety and sleep disorders. Among the medications commonly prescribed for these purposes are the following:

- **Benzodiazepines**, such as diazepam (Valium) and alprazolam (Xanax), are sometimes prescribed to treat anxiety, acute stress reactions, and panic attacks. The more sedating benzodiazepines, such as triazolam (Halcion) and estazolam (ProSom) are prescribed for short-term treatment of sleep disorders. Usually, benzodiazepines are not prescribed for long-term use because of the risk for developing tolerance, dependence, or addiction.

- **Non-benzodiazepine sleep medications**, such as zolpidem (Ambien), eszopiclone (Lunesta), and zalepon (Sonata), have a different chemical structure, but act on some of the same brain receptors as benzodiazepines. They are thought to have fewer side effects and less risk of dependence than benzodiazepines.
- **Barbiturates**, such as mephobarbital (Mebaral), phenobarbital (Luminal Sodium), and pentobarbital sodium (Nembutal), are used less frequently to reduce anxiety or to help with sleep problems because of their higher risk of overdose compared to benzodiazepines. However, they are still used in surgical procedures and for seizure disorders.

#### How do CNS depressants affect the brain and body?

Most CNS depressants act on the brain by affecting the neurotransmitter gamma-aminobutyric acid (GABA). Neurotransmitters are brain chemicals that facilitate communication between brain cells. Although the different classes of CNS depressants work in unique ways, it is through their ability to increase GABA—and thereby inhibit brain activity—that they produce a drowsy or calming effect beneficial to those suffering from anxiety or sleep disorders.



#### What are the possible consequences of CNS depressant use and abuse?

Despite their many beneficial effects, benzodiazepines and barbiturates have the potential for abuse and should be used only as prescribed. The use of non-benzodiazepine sleep aids is less well studied, but certain indicators have raised concern about their abuse liability as well. During the first few days of taking a prescribed CNS depressant, a person usually feels sleepy and uncoordinated, but as the body becomes accustomed to the effects of the drug and tolerance develops, these side effects begin to disappear. If one uses these drugs long term, larger doses may be needed to achieve the therapeutic effects. Continued use can also lead to physical dependence and withdrawal when use is abruptly reduced or stopped (see text box on “Dependence vs. Addiction” on page 3). Because all CNS depressants work by slowing the brain’s activity, when

an individual stops taking them, there can be a rebound effect, resulting in seizures or other harmful consequences. Although withdrawal from benzodiazepines can be problematic, it is rarely life threatening, whereas withdrawal from prolonged use of barbiturates can have life-threatening complications. Therefore, someone who is thinking about discontinuing CNS depressant therapy or who is suffering withdrawal from a CNS depressant should speak with a physician or seek immediate medical treatment.

#### Is it safe to use CNS depressants with other medications?

Only under a physician’s supervision is it safe to use CNS depressants with other medications. Typically, they should not be combined with any other medication or substance that causes CNS depression, including prescription pain medicines, some OTC cold and allergy medications, and alcohol. Using CNS depressants with these other substances—particularly alcohol—can affect heart rhythm, slow respiration, and even lead to death.

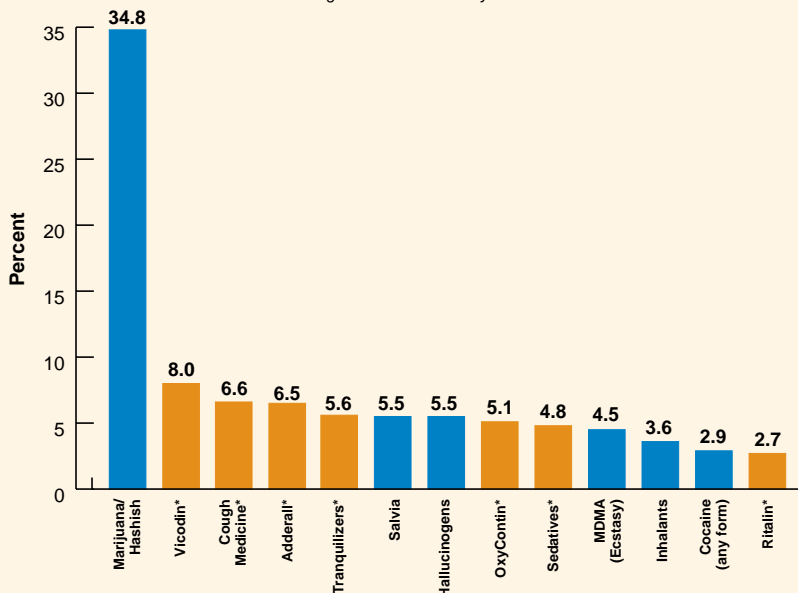




## After Marijuana, Prescription and Over-the-Counter Medications\* Account for Most of the Commonly Abused Drugs

Prevalence of Past-Year Drug Use Among 12th Graders

Categories are not mutually exclusive



SOURCE: University of Michigan, 2010 Monitoring the Future Study

\* Nonmedical Use

only a few health conditions, including ADHD, narcolepsy, and occasionally depression—in those who have not responded to other treatments.

### How do stimulants affect the brain and body?

Stimulants, such as dextroamphetamine (Dexedrine and Adderall) and methylphenidate (Ritalin and Concerta), act in the brain similarly to a family of key brain neurotransmitters called monoamines, which include norepinephrine and dopamine. Stimulants enhance the effects of these chemicals in the brain. The associated increase in dopamine can induce a feeling of euphoria when stimulants are taken nonmedically. Stimulants also increase blood pressure and heart rate, constrict blood vessels, increase blood glucose, and open up breathing passages.

## Stimulants—

### What are stimulants?

As the name suggests, stimulants increase alertness, attention, and energy, as well as elevate blood pressure, heart rate, and respiration. Stimulants historically were used to treat asthma and other respiratory problems, obesity, neurological disorders, and a variety of other ailments. But as their potential for abuse and addiction became apparent, the medical use of stimulants began to wane. Now, stimulants are prescribed to treat

## Cognitive Enhancers

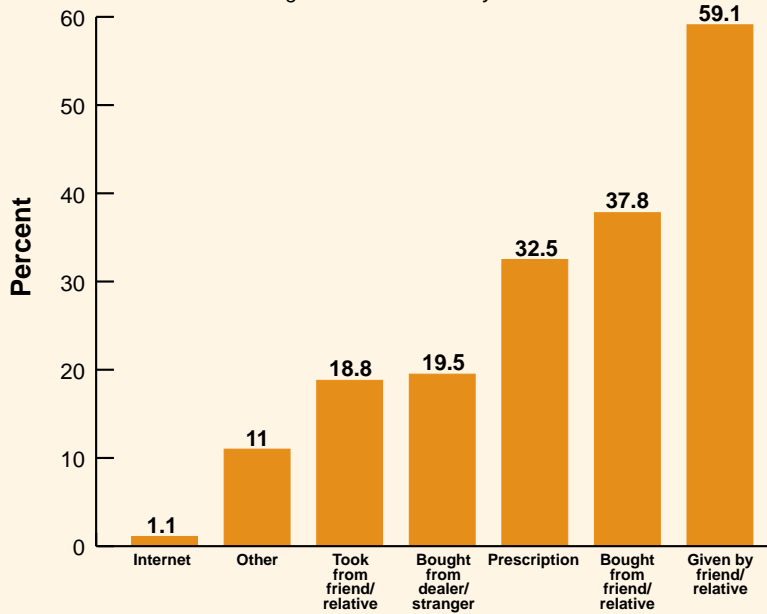
The dramatic increases in stimulant prescriptions over the last 2 decades have led to their greater environmental availability and increased risk for diversion and abuse. For those who take these medications to improve properly diagnosed conditions, they can be transforming, greatly enhancing a person's quality of life. However, because they are perceived by many to be generally safe and effective, prescription stimulants, such as Concerta or Adderall, are increasingly being abused to address nonmedical conditions or situations. Indeed, reports suggest that the practice is occurring among some academic professionals, athletes, performers, older people, and both high school and college students. Such nonmedical cognitive enhancement poses potential health risks, including addiction, cardiovascular events, and psychosis.



**Youth who abuse prescription medications are also more likely to report use of other drugs.**

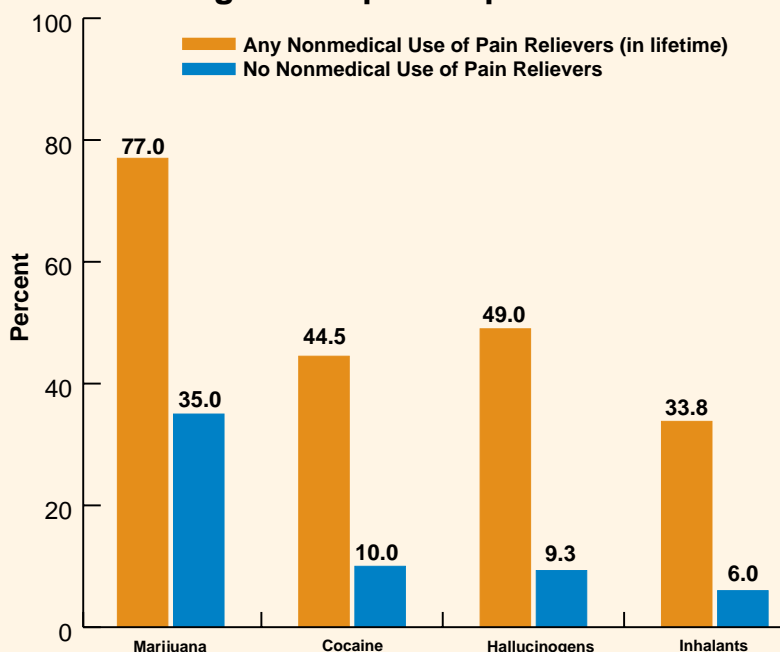
## Source of Prescription Narcotics among Those Who Used in the Past-Year, 12th Grade\*

\* Categories are not mutually exclusive



SOURCE: University of Michigan, 2010 Monitoring the Future Study

## Greater Lifetime Use of Illicit Drugs among Prescription Opiate Abusers



The rate of use of other drugs is significantly higher among those who have abused prescription drugs in their lifetimes. The same is true for past-year users.

SOURCE: SAMHSA. Misuse of prescription drugs: Data from the 2002, 2003, and 2004 National Surveys on Drug Use and Health. HHS Pub. No. (SMA)06-4192. Rockville, MD: Office of Applied Studies, 2006.

## What are the possible consequences of stimulant use and abuse?

As with other drugs of abuse, it is possible for individuals to become dependent upon or addicted to stimulants. Withdrawal symptoms associated with discontinuing stimulant use include fatigue, depression, and disturbance of sleep patterns. Repeated abuse of some stimulants (sometimes within a short period) can lead to feelings of hostility or paranoia, even psychosis. Further, taking high doses of a stimulant may result in dangerously high body temperature and an irregular heartbeat. There is also the potential for cardiovascular failure or seizures.

## Is it safe to use stimulants with other medications?

Stimulants should not be used with other medications unless authorized by a physician. Patients also should be aware of the dangers associated with mixing stimulants and OTC cold medicines that contain decongestants, as combining these substances may cause blood pressure to become dangerously high or lead to irregular heart rhythms.

## Trends in prescription drug abuse

### How many people abuse prescription drugs?

According to results from the 2010 National Survey on Drug Use and Health (NSDUH), an estimated 2.4 million Americans used prescription drugs nonmedically for the first time within the past year,

which averages to approximately 6,600 initiates per day. More than one-half were females and about a third were aged 12 to 17. Although prescription drug abuse affects many Americans, certain populations, such as youth, older adults, and women, may be at particular risk.

### Adolescents and young adults

Abuse of prescription drugs is highest among young adults aged 18 to 25, with 5.9 percent reporting nonmedical use in the past month (NSDUH, 2010). Among youth aged 12 to 17, 3.0 percent reported past-month nonmedical use of prescription medications.

According to the 2010 MTF, prescription and OTC drugs are among the most commonly abused drugs by 12th graders (see figure on page 6), after alcohol, marijuana, and tobacco. While past-year nonmedical use of sedatives and tranquilizers decreased among 12th graders over the last 5 years, this is not the case for the nonmedical use of amphetamines or opioid pain relievers.

When asked how prescription opioids were obtained for nonmedical use, more than half of the 12th graders surveyed said they were given the drugs or bought them from a friend or



relative. Interestingly, the number of students who purchased opioids over the Internet was negligible (see top chart on previous page).

Youth who abuse prescription medications are also more likely to report use of other drugs. Multiple studies have revealed associations between prescription drug abuse and higher rates of cigarette smoking; heavy episodic drinking; and marijuana, cocaine, and other illicit drug use among adolescents, young adults, and college students in the United States (see bottom chart on previous page).

### Older adults

Persons aged 65 years and older comprise only 13 percent of the population, yet account for more than one-third of total outpatient spending on prescription medications in the United States. Older patients are more likely to be prescribed long-term and multiple prescriptions, and some experience cognitive decline, which could lead to improper use of medications. Alternatively, those on a fixed income may abuse another person's remaining medication to save money.

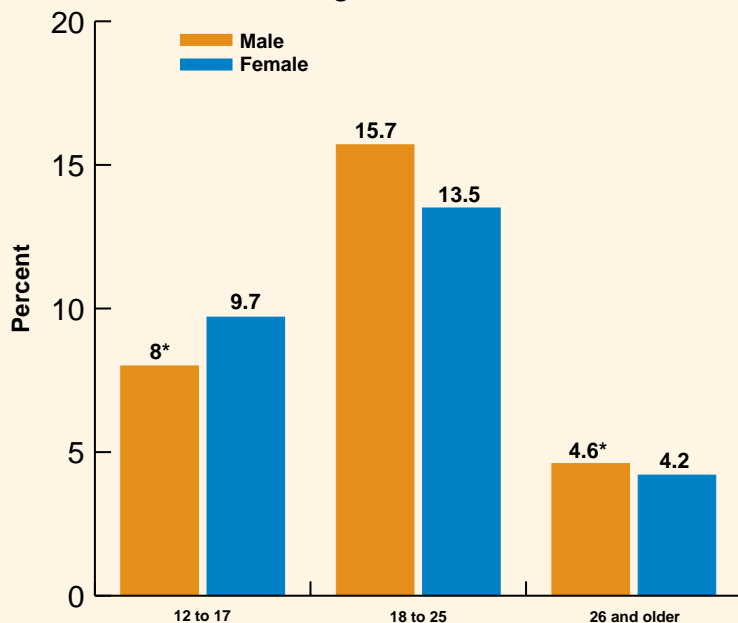
The high rates of comorbid illnesses in older populations, age-related changes in drug metabolism, and the potential for drug interactions may make any of these practices more dangerous than in younger populations. Further, a large percentage of older adults also use OTC medicines and dietary supplements, which (in addition to alcohol) could compound any adverse health consequences resulting from prescription drug abuse.



***Older patients are more likely to be prescribed long-term and multiple prescriptions, which could lead to improper use of medications.***

### Past-Year Nonmedical Use of Psychotherapeutics Among Persons 12 or Older, by Gender and Age Group

Annual averages based on 2002-2005



\* Difference from male to female significant at  $p < 0.01$ .

SOURCE: Cotto, J.H., et al. Gender effects on drug use, abuse, and dependence: An analysis of results from the National Survey on Drug Use and Health. *Gend Med* 7(5):402-413, 2010.

### Gender differences

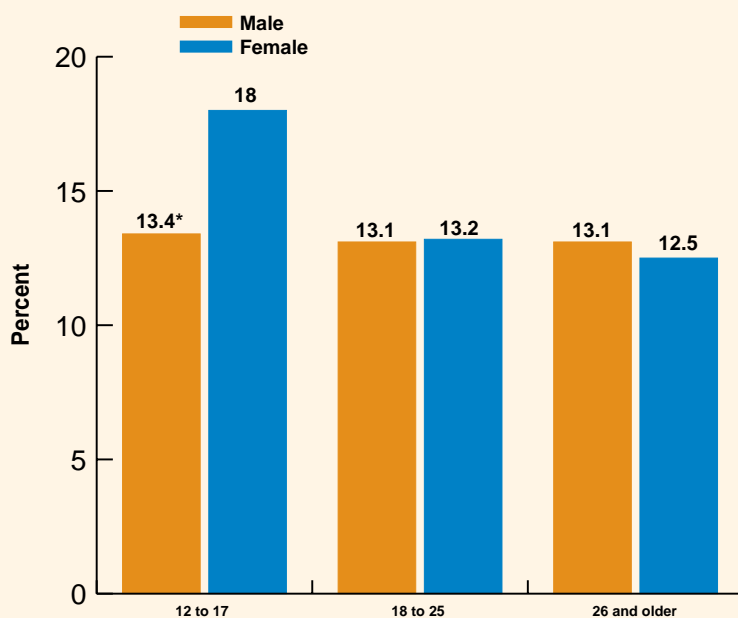
Overall, more males than females abuse prescription drugs in all age groups except the youngest (aged 12 to 17 years); that is, females in this age group exceed males in the nonmedical use of *all* psychotherapeutics, including pain relievers, tranquilizers, and stimulants. Among *nonmedical users* of prescription drugs, females 12 to 17 years old are also more likely to meet abuse or dependence criteria for psychotherapeutics (see figure, left).

### How many people suffer adverse health consequences from abusing prescription drugs?

The Drug Abuse Warning Network (DAWN), which monitors emergency department (ED) visits in selected areas across the Nation, reported that approximately 1 million ED visits in 2009 could be attributed to prescription drug abuse. Roughly 343,000 involved prescription opioid pain relievers, a rate more than double that of 5 years prior. ED visits also more than doubled for CNS stimulants, involved in nearly 22,000 visits in 2009, as well as CNS depressants (anxiolytics, sedatives, and hypnotics), involved in 363,000 visits. Of the latter, benzodiazepines (e.g., Xanax) comprised the vast majority. Rates for a popular prescribed non-benzodiazepine sleep aid, zolpidem (Ambien), rose from roughly 13,000 in 2004 to 29,000 in 2009. More than half of ED visits for prescription drug abuse involved multiple drugs.

### Past-Year Dependence or Abuse of Psychotherapeutics Among Past-Year Nonmedical Users 12 or Older, by Gender and Age Group

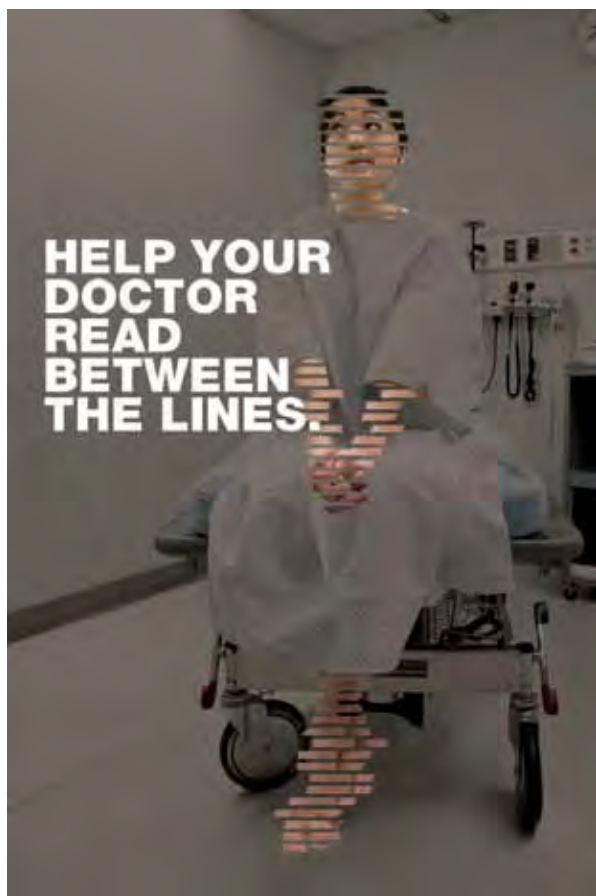
Annual averages based on 2002-2005



\* Difference from male to female significant at  $p < 0.01$ .

SOURCE: Cotto, J.H., et al. Gender effects on drug use, abuse, and dependence: An analysis of results from the National Survey on Drug Use and Health. *Gend Med* 7(5):402-413, 2010.





*To ensure proper medical care, patients should discuss any and all drug use—including prescription and over-the-counter medications—with their doctors.*

## Preventing and recognizing prescription drug abuse

The risks for addiction to prescription drugs increase when they are used in ways other than as prescribed (e.g., at higher doses, by different routes of administration, or combined with alcohol or other drugs). Physicians, their patients, and pharmacists all can play a role in identifying and preventing prescription drug abuse.

**Physicians.** More than 80 percent of Americans had contact with a healthcare professional in the past year, placing doctors in a unique position, not only to prescribe medications, but also to identify abuse (or nonmedical use) of prescription drugs and prevent the escalation to addiction. By asking about *all* drugs, physicians can help their patients recognize that a problem exists, set recovery goals, and seek appropriate treatment. Screening for prescription drug abuse can be incorporated into routine medical

visits. Doctors should also take note of rapid increases in the amount of medication needed or frequent, unscheduled refill requests. Doctors should be alert to the fact that those addicted to prescription drugs may engage in “doctor shopping”—moving from provider to provider—in an effort to obtain multiple prescriptions for the drug(s) they abuse.

Preventing or stopping prescription drug abuse is an important part of patient care. However, healthcare providers should not avoid prescribing stimulants, CNS depressants, or opioid pain relievers if needed. (See text box on “Chronic Pain Treatment and Addiction” on page 13.)

**Patients.** For their part, patients can take steps to ensure that they use prescription medications appropriately: always follow the prescribed directions, be aware of potential interactions with other drugs, never stop or change a dosing regimen without first discussing it with a healthcare provider, and never use another person’s prescription. In addition to describing their medical problem, patients should always inform their healthcare professionals about all the prescriptions, OTC medicines, and dietary and herbal supplements they are taking, before they obtain any other medications. Additionally, unused or expired medications should be properly



***Prescription Drug Monitoring Programs allow physicians and pharmacists to track prescriptions and help identify patients who are “doctor shopping.”***

discarded per U.S. Food and Drug Administration (FDA) guidelines or at U.S. Drug Enforcement Administration collection sites.

**Pharmacists.** Pharmacists dispense medications and can help patients understand instructions for taking them. By being watchful for prescription falsifications or alterations, pharmacists can serve as the first line of defense in recognizing prescription drug abuse. Some pharmacies have developed hotlines to alert other pharmacies in the region when a fraudulent prescription is detected. Moreover, prescription drug monitoring programs (PDMPs), which require physicians and pharmacists to log each filled prescription into a State database, can assist medical professionals in identifying patients who are getting prescriptions from multiple sources. As of May 2011, 48 States and 1 territory have enacted legislation authorizing PDMPs, 34 of which are operational.

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## Treating prescription drug addiction

Years of research have shown that addiction to any drug (illicit or prescribed) is a brain disease that can be treated effectively. Treatment must take into account the type of drug used and the needs of the individual. Successful treatment may need to incorporate several components, including detoxification, counseling, and sometimes the use of addiction medications. Multiple courses of treatment may be needed for the patient to make a full recovery.



*Although a behavioral or pharmacological approach alone may be sufficient for treating some patients, research shows that a combined approach may be best.*

The two main categories of drug addiction treatment are behavioral and pharmacological. Behavioral treatments help patients stop drug use by teaching them strategies to function without drugs, deal with cravings, avoid drugs and situations that could lead to drug use, and handle a relapse should it occur. When delivered effectively, behavioral treatments, such as individual counseling, group or family counseling, contingency management, and cognitive-behavioral therapies, also can help patients improve their personal relationships and their ability to function at work and in the community.

Some addictions, such as opioid addiction, can be treated with medications. These pharmacological treatments counter the effects of the drug on the brain and behavior, and

can be used to relieve withdrawal symptoms, help overcome drug cravings, or treat an overdose. Although a behavioral or pharmacological approach alone may be sufficient for treating some patients, research shows that a combined approach may be best.

### Treating addiction to prescription opioids

Several options are available for effectively treating prescription opioid addiction. These options are drawn from research on the treatment of heroin addiction and include medications (e.g., naltrexone, methadone, and buprenorphine) as well as behavioral counseling approaches.

Naltrexone is an *antagonist* medication that prevents opioids from activating their receptors. It is used to treat overdose and addiction, although its use for addiction has been limited due to



poor adherence and tolerability by patients. Recently, an injectable, long-acting form of naltrexone (Vivitrol), originally approved for treating alcoholism, has also received FDA approval to treat opioid addiction (i.e., heroin or other opioids). Because its effects last for weeks, Vivitrol is ideal for patients who do not have ready access to healthcare or who struggle with taking their medications regularly. Methadone is a synthetic opioid *agonist* that eliminates withdrawal symptoms and relieves drug cravings by acting on the same brain targets as other opioids like heroin, morphine, and opioid pain medications. It has been used successfully for more than 40 years to treat heroin addiction, but must be dispensed through opioid treatment programs. Buprenorphine is a partial opioid agonist (i.e., it has agonist and antagonist properties), which can be prescribed by certified physicians in an office setting. Like methadone, it

can reduce cravings and is well tolerated by patients. NIDA is supporting research needed to determine the effectiveness of these medications in treating addiction to opioid pain relievers.

#### **Treating addiction to CNS depressants**

Patients addicted to barbiturates and benzodiazepines should not attempt to stop taking them on their own. Withdrawal symptoms from these drugs can be problematic, and—in the case of certain CNS depressants—potentially life-threatening. Research on treating barbiturate and benzodiazepine addiction is sparse; however, addicted patients should undergo medically supervised detoxification because the dosage they take should be gradually tapered. Inpatient or outpatient counseling can help individuals through this process. Cognitive-behavioral therapy, which focuses on modifying the patient's thinking,

expectations, and behaviors while increasing skills for coping with various life stressors, also has been used successfully to help individuals adapt to discontinuing benzodiazepines.

Often barbiturate and benzodiazepine abuse occurs in conjunction with the abuse of other drugs, such as alcohol or cocaine. In such cases of polydrug abuse, the treatment approach should address the multiple addictions.

#### **Treating addiction to prescription stimulants**

Treatment of addiction to prescription stimulants, such as Adderall and Concerta, is based on behavioral therapies used in treating cocaine and methamphetamine addiction. At this time, there are no medications that are FDA-approved for treating stimulant addiction. Thus, NIDA is supporting research in this area.

Depending on the patient's situation, the first steps in treating prescription stimulant addiction may be to taper the drug dosage and attempt to ease withdrawal symptoms. The detoxification process could then be followed by behavioral therapy. Contingency management, for example, uses a system that enables patients to earn vouchers for drug-free urine tests. (These vouchers can be exchanged for items that promote healthy living.) Cognitive-behavioral therapy also may be an effective treatment for addressing stimulant addiction. Finally, recovery support groups may be helpful in conjunction with behavioral therapy.



## Chronic Pain Treatment and Addiction

Healthcare providers have long wrestled with how best to treat patients who suffer from chronic pain, roughly 116 million in this country. Their dilemma stems from the potential risks involved with long-term treatment, such as the development of drug tolerance (and the need for escalating doses), hyperalgesia (increased pain sensitivity), and addiction. Patients themselves may even be reluctant to take an opioid medication prescribed to them for fear



of becoming addicted. Estimates of addiction among chronic pain patients vary widely—from about 3 percent to 40 percent. This variability is the result of differences in treatment duration, insufficient research on long-term outcomes, and disparate study populations and measures used to assess abuse or addiction.

To mitigate addiction risk, physicians should screen patients for potential risk factors, including personal or family history of drug abuse or mental illness. Monitoring patients for signs of abuse is also crucial, and yet some indicators can signify multiple conditions, making accurate assessment challenging. Early or frequent requests for prescription pain medication refills, for example, could represent illness progression, the development of drug tolerance, or the emergence of a drug problem.

The development of effective, nonaddicting pain medications is a public health priority. A growing elderly population and an increasing number of injured military only add to the urgency of this issue. Researchers are exploring alternative medications that can alleviate pain but have less abuse potential. More research is needed to better understand effective chronic pain management, including identifying factors that predispose some patients to addiction and developing measures to prevent abuse.

## Glossary

**Addiction:** A chronic, relapsing disease characterized by compulsive drug seeking and use, despite serious adverse consequences, and by long-lasting changes in the brain.

**Agonist:** A chemical entity that binds to a receptor and activates it, mimicking the action of the natural (or abused) substance that binds there.

**Antagonist:** A chemical entity that binds to a receptor and blocks its activation. Antagonists prevent the natural (or abused) substance from activating its receptor.

**Barbiturate:** A type of CNS depressant prescribed to promote sleep (usually in surgical procedures) or as an anticonvulsant.

**Benzodiazepine:** A type of CNS depressant prescribed to relieve anxiety and sleep problems. Valium and Xanax are among the most widely prescribed medications.

**Buprenorphine:** A mixed opiate agonist/antagonist medication approved by the FDA in October 2002 for the treatment of opioid addiction (e.g., heroin).

**Central Nervous System:** The brain and spinal cord.

**CNS Depressants:** A class of drugs that slow CNS function (also called sedatives and tranquilizers), some of which are used to treat anxiety and sleep disorders; includes barbiturates and benzodiazepines.

**Comorbidity:** The occurrence of two disorders or illnesses in the same person, also referred to as co-occurring conditions or dual diagnosis. Patients with comorbid illnesses may experience a more severe illness course and require treatment for each or all conditions.

**Detoxification:** A process in which the body rids itself of a drug (or its metabolites). During this period, withdrawal symptoms can emerge that may require medical treatment. This is often the first step in drug abuse treatment.

**Dopamine:** A brain chemical, classified as a neurotransmitter, found in regions that regulate movement, emotion, motivation, and pleasure.

**Methadone:** A long-acting synthetic opioid medication that is effective in treating opioid addiction and pain.

**Narcolepsy:** A disorder characterized by uncontrollable episodes of deep sleep.

**Norepinephrine:** A neurotransmitter present in the brain and the peripheral (sympathetic) nervous system; and a hormone released by the adrenal glands. Norepinephrine is involved in attention, responses to stress, and it regulates smooth muscle contraction, heart rate, and blood pressure.

**Opioid:** A compound or drug that binds to receptors in the brain involved in the control of pain and other functions (e.g., morphine, heroin, hydrocodone, oxycodone).

**Physical Dependence:** An adaptive physiological state that occurs with regular drug use and results in a withdrawal syndrome when drug use is stopped; often occurs with tolerance. Physical dependence can happen with chronic—even appropriate—use of many medications, and by itself does not constitute addiction.

**Polydrug Abuse:** The abuse of two or more drugs at the same time, such as CNS depressants and alcohol.

**Prescription Drug Abuse:** The use of a medication without a prescription; in a way other than as prescribed; or for the experience or feeling elicited. This term is used interchangeably with “nonmedical” use, a term employed by many of the national surveys.

**Psychotherapeutics:** Drugs that have an effect on the function of the brain and that often are used to treat psychiatric/neurologic disorders; includes opioids, CNS depressants, and stimulants.

**Respiratory Depression:** Slowing of respiration (breathing) that results in the reduced availability of oxygen to vital organs.

**Sedatives:** Drugs that suppress anxiety and promote sleep; the NSDUH classification includes benzodiazepines, barbiturates, and other types of CNS depressants.

**Stimulants:** A class of drugs that enhances the activity of monamines (such as dopamine) in the brain, increasing arousal, heart rate, blood pressure, and respiration, and decreasing appetite; includes some medications used to treat attention-deficit hyperactivity disorder (e.g., methylphenidate and amphetamines), as well as cocaine and methamphetamine.

**Tolerance:** A condition in which higher doses of a drug are required to produce the same effect achieved during initial use; often associated with physical dependence.

**Tranquilizers:** Drugs prescribed to promote sleep or reduce anxiety; the NSDUH classification includes benzodiazepines, barbiturates, and other types of CNS depressants.

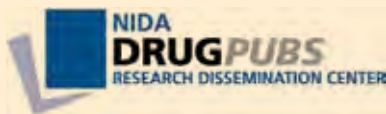
**Withdrawal:** Symptoms that occur after chronic use of a drug is reduced abruptly or stopped.

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## Where Can I Get More Scientific Information on Prescription Drug Abuse?

To learn more about prescription drugs and other drugs of abuse, or to order materials on these topics free of charge in English or Spanish, visit the NIDA Web site at [www.drugabuse.gov](http://www.drugabuse.gov) or contact the *DrugPubs* Research Dissemination Center at 877-NIDA-NIH (877-643-2644; TTY/TDD: 240-645-0228).



### What's New on the NIDA Web Site

- Information on drugs of abuse
- Publications and communications (including *NIDA Notes* and *Addiction Science & Clinical Practice journal*)
- Calendar of events
- Links to NIDA organizational units
- Funding information (including program announcements and deadlines)
- International activities
- Links to related Web sites (access to Web sites of many other organizations in the field)

### NIDA Web Sites

[drugabuse.gov](http://drugabuse.gov)  
[backtoschool.drugabuse.gov](http://backtoschool.drugabuse.gov)  
[clubdrugs.gov](http://clubdrugs.gov)  
[teens.drugabuse.gov](http://teens.drugabuse.gov)

### For Physician Information



[www.drugabuse.gov/nidamed](http://www.drugabuse.gov/nidamed)

### Other Web Sites

Information on prescription drug abuse is also available through the following Web site:

- Substance Abuse and Mental Health Services Administration Health Information Network:  
[www.samhsa.gov/shin](http://www.samhsa.gov/shin)

## U.S. Department of Health and Human Services

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## Part B: 20 Questions and Answers Regarding Methadone Maintenance Treatment Research

### Question 1: Is methadone maintenance treatment effective for opioid addiction?

**Answer:** Yes. Research has demonstrated that methadone maintenance treatment is an effective treatment for heroin and prescription narcotic addiction when measured by

- Reduction in the use of illicit drugs
- Reduction in criminal activity
- Reduction in needle sharing
- Reduction in HIV infection rates and transmission
- Cost-effectiveness
- Reduction in commercial sex work
- Reduction in the number of reports of multiple sex partners
- Improvements in social health and productivity
- Improvements in health conditions
- Retention in addiction treatment
- Reduction in suicide
- Reduction in lethal overdose

### Research Highlights

- Recent meta-analyses have supported the efficacy of methadone for the treatment of opioid dependence. These studies have demonstrated across countries and populations that methadone can be effective in improving treatment retention, criminal activity, and heroin use (Mattick, Breen, Kimber, et al., 2003; Marsch, 1998).
- An overview of 5 meta-analyses and systematic reviews, summarizing results from 52 studies and 12,075 opioid-dependent participants, found that when methadone maintenance treatment was compared with methadone detoxification treatment, no treatment, different dosages of methadone, buprenorphine maintenance treatment, heroin maintenance treatment, and L-a-acetylmethadol (LAAM) maintenance treatment, methadone maintenance treatment was more effective than detoxification, no treatment, buprenorphine, LAAM, and heroin plus methadone. High doses of methadone are more effective than medium and low doses (Amato, Davoli, Perucci, et al., 2005).
- Patients receiving methadone maintenance treatment exhibit reductions in illicit opioid use that are directly related to methadone dose, the amount of psychosocial counseling, and the period of time that patients stay in treatment. Patients receiving methadone doses of 80 to 100 mg have improved treatment retention and decreased illicit drug use compared with patients receiving 50 mg of methadone (Strain, Bigelow, Liebson, et al., 1999). Patients staying in treatment for longer periods of time showed greater improvements than those who stayed in treatment for shorter periods (Sells and Simpson, 1976; Simpson, 1993).
- A systematic review conducted on 28 studies involving 7,900 patients has demonstrated significant reductions in HIV risk behaviors in patients receiving methadone maintenance (Gowing, Farrell, Bornemann, et al., 2004). In one study that followed two separate cohorts of HIV-negative injection opioid users, HIV seroconversion occurred in 22 percent of 103 out-of-

treatment subjects compared with 3.5 percent of 152 subjects receiving methadone (Metzger, Woody, McLellan, et al., 1993).

- A randomized clinical trial in Bangkok, Thailand, included 240 heroin-dependent patients, all of whom had previously undergone at least 6 detoxification episodes. The patients were randomly assigned to methadone maintenance versus 45-day methadone detoxification. The study found that the methadone maintenance patients were more likely to complete 45 days of treatment, less likely to have used heroin during treatment, and less likely to have used heroin on the 45th day of treatment (Vanichseni, Wongsuwan, Choopanya, et al., 1991).
- In the Treatment Outcome Prospective Study (TOPS), methadone maintenance patients who remained in treatment for at least 3 months experienced dramatic improvements during treatment with regard to daily illicit opioid use, cocaine use, and predatory crime. These improvements persisted for 3 to 5 years following treatment, but at reduced levels (Hubbard, Marsden, Rachal, et al., 1989).
- In a study of 933 heroin-dependent patients in methadone maintenance treatment programs, during episodes of methadone maintenance, there were (1) decreases in narcotic use, arrests, criminality, and drug dealing; (2) increases in employment and marriage; and (3) diminished improvements in areas such as narcotic use, arrest, criminality, drug dealing, and employment for patients who relapsed (Powers and Anglin, 1993).
- In a 2.5-year followup study of 150 opioid-dependent patients, participation in methadone maintenance treatment resulted in a substantial improvement along several relatively independent dimensions, including medical, social, psychological, legal, and employment problems (Kosten, Rounsaville, and Kleber, 1987).
- A study that compared ongoing methadone maintenance with 6 months of methadone maintenance followed by detoxification demonstrated that methadone maintenance resulted in greater treatment retention (median, 438.5 vs. 174.0 days) and lower heroin use rates than did detoxification. Methadone maintenance therapy resulted in a lower rate of drug-related (mean [SD] at 12 months, 2.17 [3.88] vs. 3.73 [6.86]) but not sex-related HIV risk behaviors and a lower score in legal status (mean [SD] at 12 months, 0.05 [0.13] vs. 0.13 [0.19]) (Sees, Delucchi, Masson, et al., 2000).

**Patient Status Before and After Methadone Maintenance Treatment**—A study by McGlothlin and Anglin (1981) examined patients from three methadone maintenance treatment programs.

Figures 1 through 5 provide the results from all three programs, which illustrate that methadone maintenance treatment is effective in improving patients' lives in terms of time spent (1) using narcotics daily, (2) unemployed, (3) involved in crime, (4) dealing drugs, and (5) incarcerated.

The left side of each graph describes patient behavior before methadone maintenance treatment, and the right side of each graph depicts patient behavior following methadone maintenance treatment, including the behavior of patients who left treatment before the year ended.

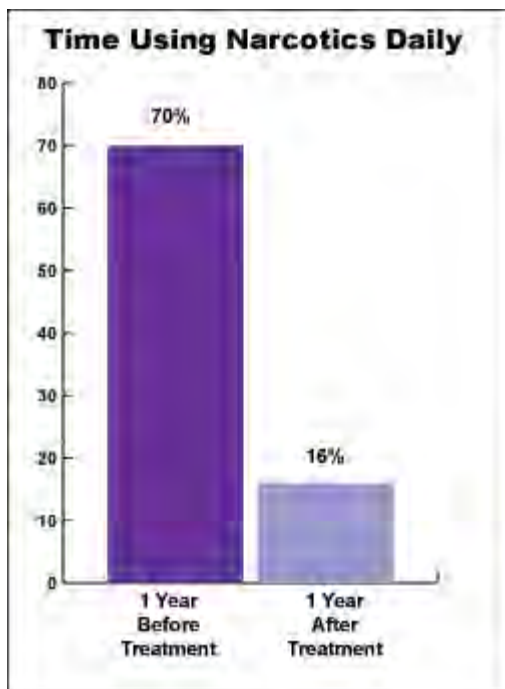


Figure 1 illustrates that the percentage of time using daily narcotics was much greater before methadone maintenance treatment than after (McGlothlin and Anglin, 1981).

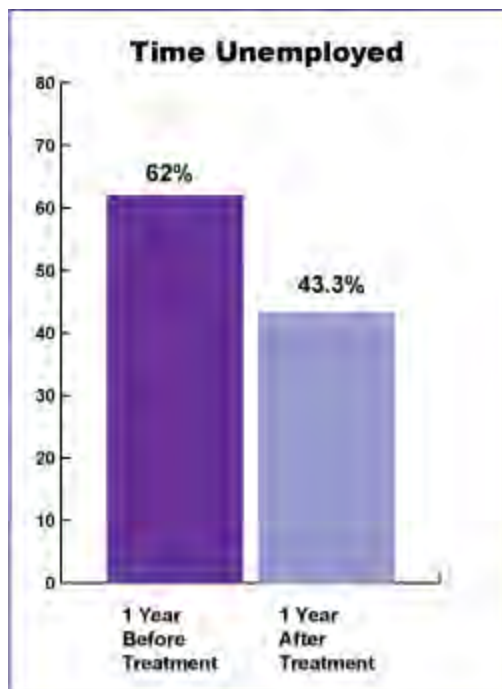


Figure 2 illustrates that the percentage of time unemployed decreased after methadone maintenance treatment (McGlothlin and Anglin, 1981).

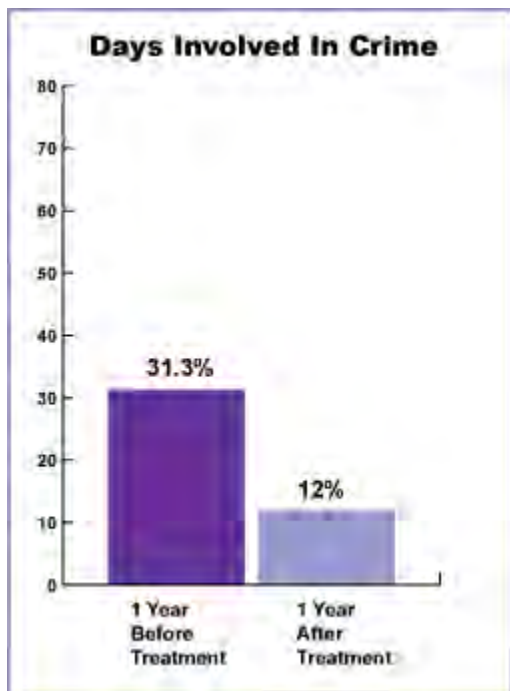


Figure 3 illustrates that the percentage of days the patient was involved in crime decreased after methadone maintenance treatment (McGlothlin and Anglin, 1981).

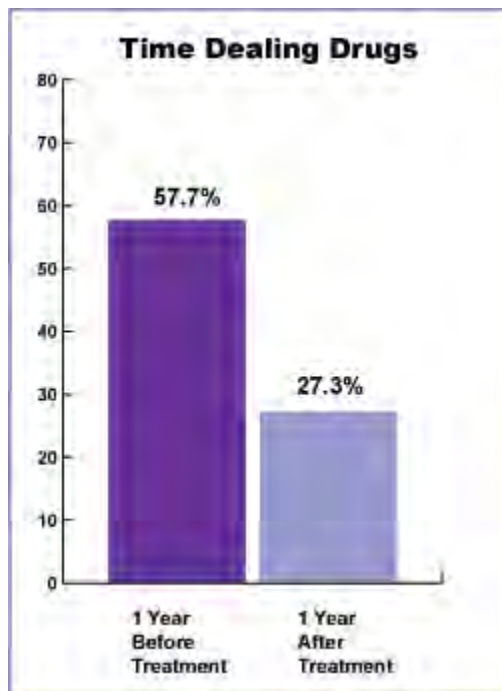
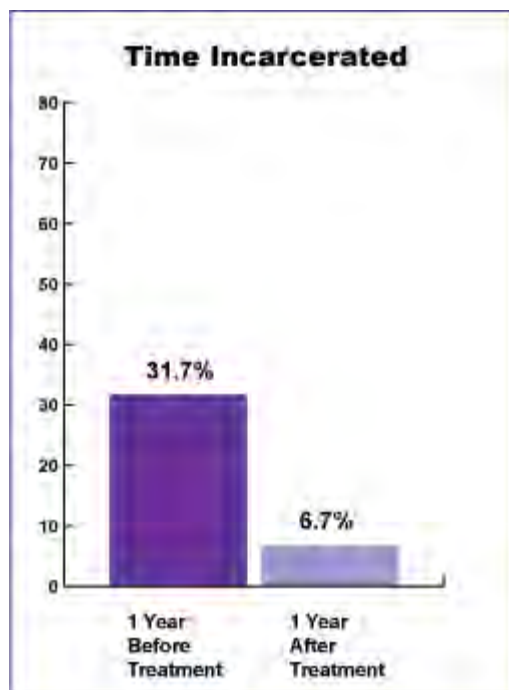


Figure 4 illustrates that the percentage of time dealing drugs decreased after methadone maintenance treatment (McGlothlin and Anglin, 1981).



**Figure 5 illustrates that the percentage of time incarcerated decreased after methadone maintenance treatment (McGlothlin and Anglin, 1981).**

### The Effects of Opioids (Heroin or Prescription Narcotics) and Methadone on Functional State—

Figures 6 and 7 illustrate how opioids and methadone have different effects on a patient's functional states and moods: repeated use of heroin or prescription narcotics causes multiple cycles of elevation and depression, but methadone promotes a relatively steady state.

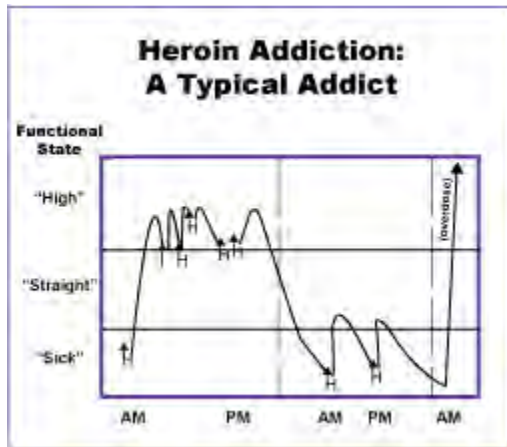
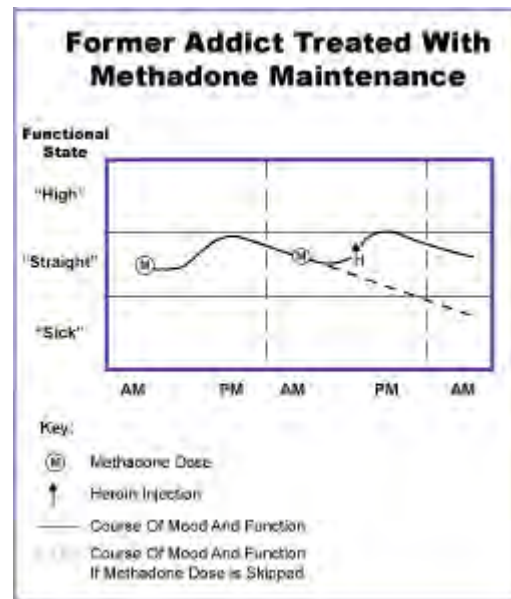
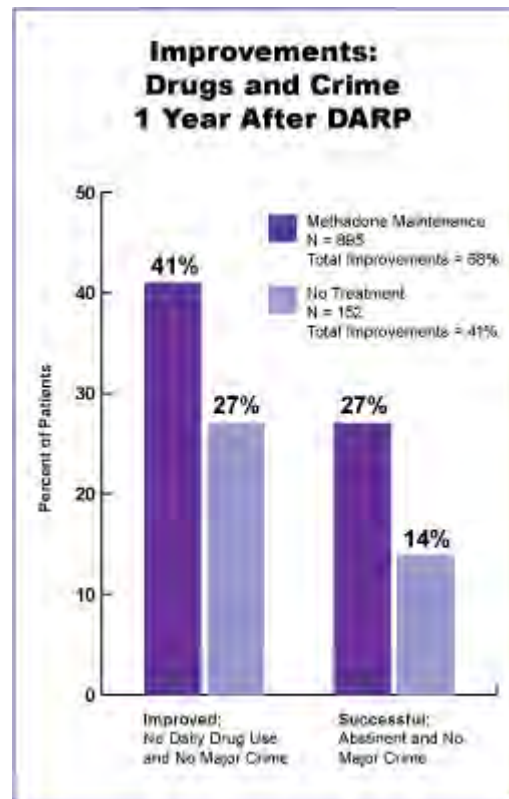


Figure 6 illustrates a typical day for a person who is opioid dependent. Note that the opioid-dependent person generally uses opioids several times each day. Each use causes an elevation in mood: the user feels "high." This high is followed by a rapid decline in mood and functional state: the user no longer feels high and may begin to feel sick. At the end of the day, or in the morning, the user feels quite sick as the result of opioid withdrawal. Overall, a typical day includes several cycles of elevated and depressed mood and functional state. As an opioid-dependent person uses opioids for a period of time (e.g., weeks to months), that person's level of physical dependence makes it less likely that he or she will experience the high. Continued drug use results from a desire to avoid the depressions and physical symptoms associated with opioid withdrawal.



In contrast, Figure 7 illustrates that a single oral dose of methadone in the morning promotes a relatively steady state of mood and function. This graph also demonstrates that use of an opioid (e.g., injection of heroin) during methadone maintenance treatment has a less intense effect on mood and function than an injection of heroin in active users who are not in methadone treatment. The dotted line in Figure 7 predicts the course of a patient's mood and function if a dose of methadone is omitted. Dole, Nyswander, and Kreek (1966) found that the decline in mood and function is gradual, not steep.

**Improvements: Drugs and Crime 1 Year After the Drug Abuse Reporting Program Study (DARP)**—The DARP study (Simpson and Sells, 1982) demonstrates that methadone maintenance treatment is effective in reducing two problems associated with heroin addiction: illicit drug use and crime. The study compared reductions in illicit drug use and crime by patients who received methadone maintenance treatment and by patients who received no treatment.



**Figure 8 illustrates that, during the first year after treatment, 41 percent of methadone maintenance treatment patients were no longer addicted to illicit opioids and were not involved in major crime. In contrast, 27 percent who received no treatment were no longer addicted to illicit opioids and were not involved in major crime (Simpson and Sells, 1982).**

Twenty-seven percent of methadone maintenance treatment patients had not used any illicit drugs and had no arrests or incarcerations during the year after methadone maintenance treatment. In contrast, 14 percent of those not treated reported no illicit drug use or arrests. Overall, 68 percent of methadone maintenance treatment patients experienced significant improvements regarding illicit drug use and crime in contrast to roughly 41 percent of those not treated.



**The Effect of Methadone Maintenance Treatment Duration on Drug Use and Crime**—The DARP study also shows that the longer patients stay in treatment, the more likely they are to remain crime free.

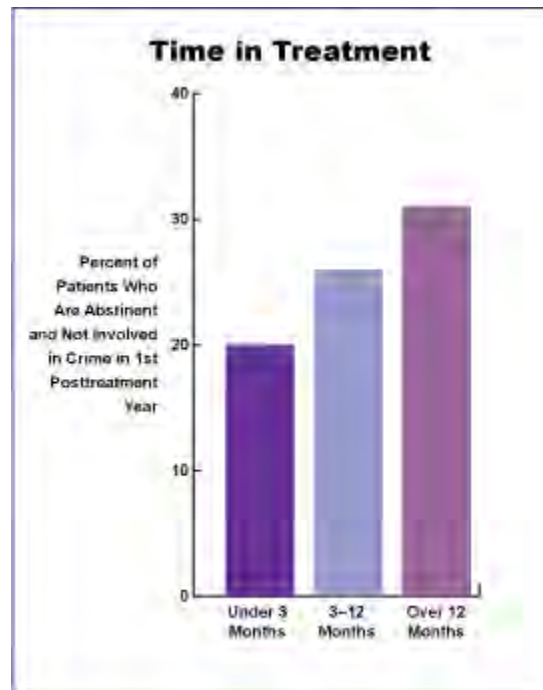


Figure 9 illustrates that there is a relationship between how long patients remain in treatment and how well they function after treatment. In this instance, the length of treatment was associated with abstinence from illicit drug use and an absence of crime. Thirty percent of patients who stayed in treatment for more than 12 months abstained from illicit drug use and criminal activity. Twenty-five percent of patients in treatment from 3 to 12 months stopped using illicit drugs and committing crimes; of those who were in treatment for under 3 months, 20 percent abstained (Simpson and Sells, 1982).

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## Question 2: Does methadone maintenance treatment reduce illicit opioid use?

**Answer:** Yes. Patients' illicit opioid use declines, often dramatically, during methadone maintenance treatment. However, adequate methadone dosage and basic psychosocial services are essential for treatment effectiveness.

### Research Highlights

Condelli and Dunteman (1993) examined a sample of 526 patients admitted to 17 methadone maintenance treatment programs that participated in the Treatment Outcome Perspective Study (TOPS). This analysis compared the length of methadone maintenance treatment with heroin use. The average short-term treatment duration was 31 days; long-term, 233 days; and continuous, 725 days. The rate of heroin use was 100 percent before treatment, 39 percent after short-term treatment, 40 percent after long-term treatment, and 17 percent after continuous treatment. This study suggests that longer exposure to methadone maintenance treatment decreases the likelihood of heroin use.

A study of 933 heroin addicts participating in methadone maintenance treatment programs compared behavior during periods on and off methadone maintenance. The study demonstrated that during periods on methadone maintenance, illicit narcotic use decreased significantly and reduction in illicit narcotic use was the most prominent effect among nine indicators of treatment success (Powers and Anglin, 1993).

In the Drug Abuse Reporting Program (DARP) study, 44 percent of the 895 patients who entered methadone maintenance treatment reported no daily use of illicit narcotics in the first posttreatment year. This represented a 56-percent decrease from 100-percent daily use in the 2 months before admission (Simpson and Sells, 1982).

### Methadone Dose

In the Ball and Ross studies (1991), patients reduced their use of injected heroin by 71 percent compared with preadmission levels. Illicit opioid use was directly related to methadone dosage: in patients on doses above 71 mg per day, no heroin use was detected, whereas patients on doses below 46 mg per day were 5.16 times more likely to use heroin than those receiving higher doses.

The impact of methadone dose has been demonstrated consistently across studies and countries. Higher (e.g., greater than 50 mg) doses of methadone are associated with better treatment retention and decreased illicit drug use (Strain, Stitzer, Liebson, et al., 1993; Strain, Bigelow, Liebson, et al., 1999; Capplehorn and Bell, 1991; Capplehorn, Bell, Kleinbaum, et al., 1993; Faggiano, Vigna-Taglianti, Versino, et al., 2003).

A meta-analysis (Faggiano et al., 2003) of 21 studies concluded that methadone dosages ranging from 60 to 100 mg per day were more effective than lower dosages in retaining patients and in reducing use of heroin and cocaine during treatment.

The following outcomes in the meta-analysis were noted:

**Retention rate**—randomized clinical trials: high versus low doses at short duration followup: RR = 1.36 [1.13 to 1.63], and at longer duration followup: RR = 1.62 [0.95 to 2.77]

**Self-reported opioid use**—randomized clinical trials: high versus low doses WMD = -2.00 [4.77 to 0.77], high versus medium doses WMD = -1.89 [-3.43 to -0.35]

**Opioid abstinence by urine toxicology at greater than 3 to 4 weeks**—randomized clinical trials: high versus low doses RR = 1.59 [1.16 to 2.18], high versus medium doses RR = 1.51 [0.63 to 3.61]

**Cocaine abstinence by urine toxicology at greater than 3 to 4 weeks**—randomized clinical trials: high versus low doses RR = 1.81 [1.15 to 2.85]

**Overdose mortality**—high dose versus low dose at 6 years' followup: RR = 0.29 [0.02 to 5.34]; high dose versus medium dose at 6 years' followup: RR = 0.38 [0.02 to 9.34]; medium dose versus low dose at 6 years' followup: RR = 0.57 [0.06 to 5.06]

One study noted lower rates of opioid-positive urine samples (53% vs. 62%,  $p < .05$ ) in patients who were being treated with 80 to 100 mg of methadone compared with those who were being treated with 40 to 50 mg (Strain et al., 1999).

### **Counseling Services**

Counseling services improve treatment outcomes over the provision of methadone alone (Amato, Minozzi, Davoli, et al., 2004). The importance of adding counseling services to methadone maintenance was demonstrated in a study that randomly assigned new patients to three levels of care: (1) methadone alone, (2) methadone plus standard counseling services, and (3) methadone plus enhanced services (counseling, medical/psychiatric, employment, and family therapy services). Patients who received the standard or enhanced services had higher treatment retention rates and less opiate use than those who received methadone alone (McLellan, Arndt, Metzger, et al., 1993). A cost-effectiveness analysis of these subjects after 1 year revealed that the standard counseling services were most cost-effective (Kraft, Rothbard, Hadley, et al., 1997).

### **Treatment Duration**

In one study, 82 percent of 105 patients who discontinued methadone relapsed to intravenous drug use within 12 months (Ball and Ross, 1991). Concerns over high relapse rates have led authorities to advocate for maintenance treatment as long as the patient (1) continues to benefit, (2) wishes to remain, (3) is at risk of relapse, (4) suffers no significant side effects, and (5) stays in treatment as long as treatment is needed, as determined by the clinician (Payte and Khuri, 1993).

DARP studies of opioid-dependent patients 12 years following admission to treatment showed that illicit opioid use declined progressively over time until year 6, when it stabilized at about 40 percent for “any” use and 25 percent for “daily” use (Simpson, Joe, Lehman, et al., 1986).

In both the DARP and TOPS studies, long treatment duration was the strongest predictor of reduced heroin use among methadone maintenance patients.

**Reductions in Illicit Opioid Use During and After Methadone Maintenance Treatment**—The DARP and TOPS studies of two different groups of heroin-addicted patients were conducted several years apart. Both demonstrated about a 40-percent reduction in illicit opioid use at the end of 1 year after methadone maintenance treatment.